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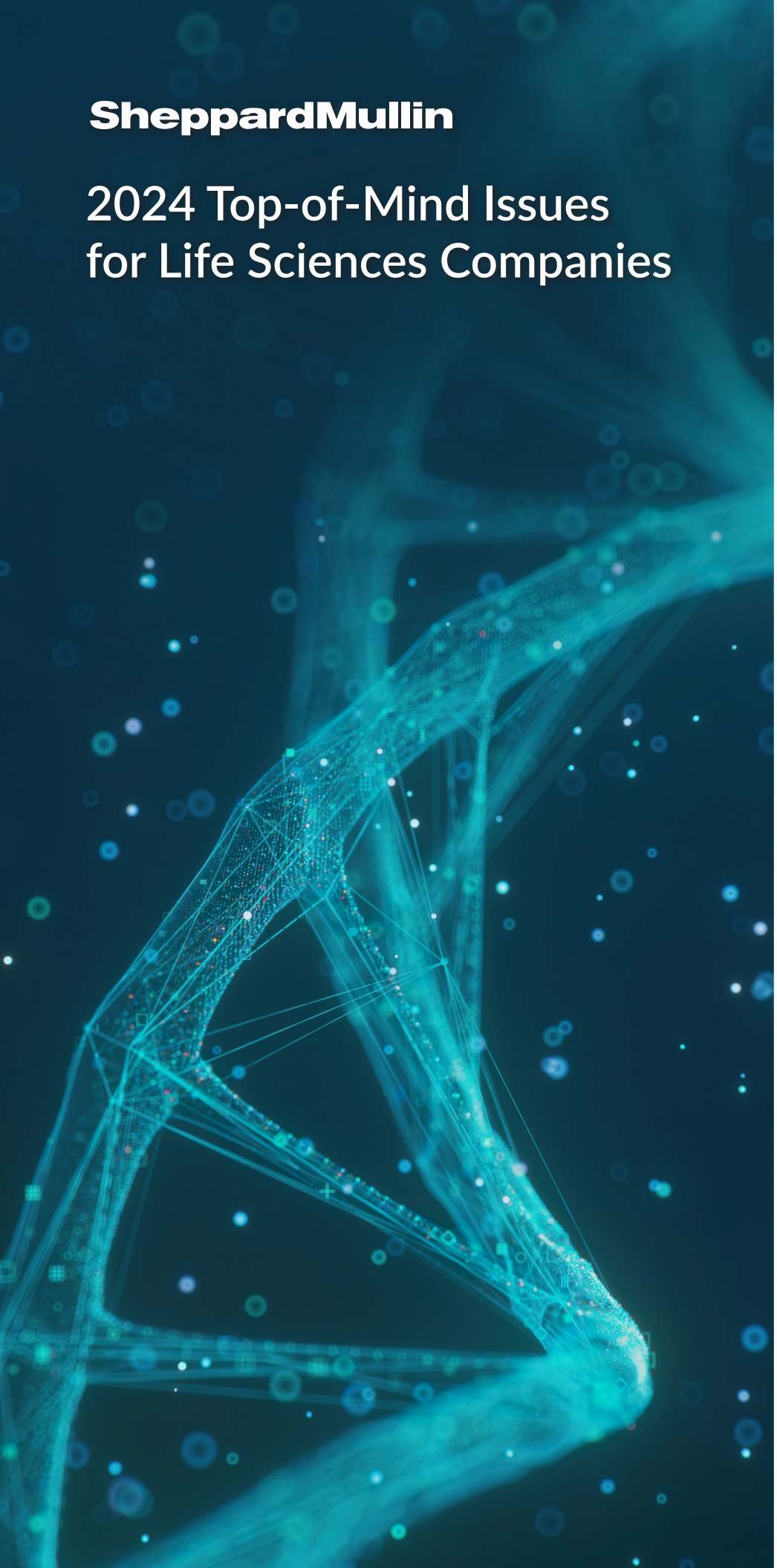
2024 Top-of-Mind Issues for Life Sciences Companies



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As we reflect on 2023 and make predictions for 2024, it is remarkable the number of significant events occurring this past year that will be impactful for the activities of the life sciences industry going forward. Although there was no single moment like the passage of the Affordable Care Act in 2010, there are numerous distinct events that will loom large in 2024 and beyond.

When the Life Sciences lawyers at Sheppard Mullin sat down to compile the articles for this year's *Top-of-Mind* publication, it became clear that substantial changes were happening in all corners of the life sciences industry. First, and most obvious, were the approvals of two groundbreaking treatments in GLP-1s and CRISPR. Much has been written about the effects of both of those, so for this publication we decided to focus on some other noteworthy developments that could have long-lasting impacts for manufacturers, from artificial intelligence to the 340B Program, to the impact of the Supreme Court's potential overturning of the *Chevron* doctrine. We hope you enjoy reading these insights and be sure to follow our blog throughout the year.

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Notable AI Developments and Privacy Considerations

By: Julie Kadish and Arushi Pandya

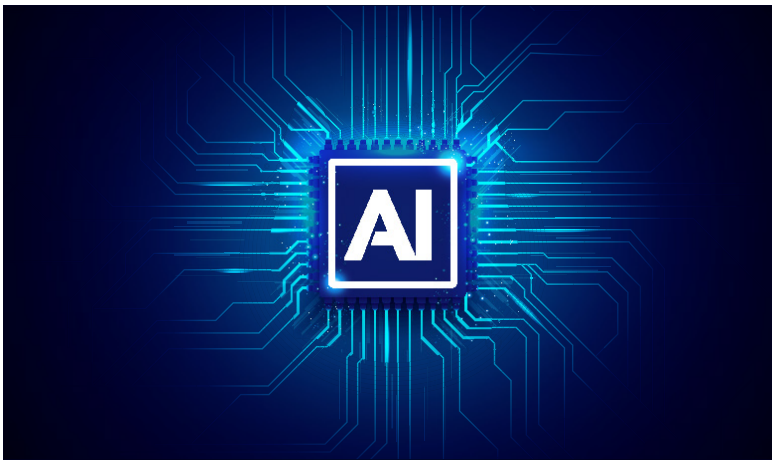
The life sciences industry is no stranger to being at the forefront of technological developments and innovation. Most recently, artificial intelligence (AI) is shaping an important role. With the potential to transform research and drug development, clinical trials, manufacturing, supply chain, and regulatory processes, AI is poised to serve a critical role for life sciences companies.

2023 catalyzed significant discussions on how to regulate AI, including at a state, federal, and international level. While there is no consensus on how best to regulate AI, there are common concerns that have emerged with privacy, data ethics, and data governance consistently permeating the AI conversation. In the wake of the rapid development and adoption of AI technologies happening across all industries, 2024 is expected to bring additional guidance and regulatory scrutiny. Below, we highlight three regulatory developments from 2023 and their role in impacting the advancement of AI as we look ahead.

European Union AI Act

In December 2023, European Union ("EU") policymakers provisionally agreed to the details of the EU AI Act ("AI Act"). This flagship legal framework marks the first comprehensive piece of AI legislation in any territory. The full text of the proposed AI Act, which was first introduced conceptually in 2021, has not yet been released. As of now, the Act would be effective two years after it is enacted and becomes a "regulation" – when it would be directly applicable in all EU member states. This makes it likely that the AI Act will come into effect sometime in 2026 (or later). That said, given the sweeping nature of the legislation, developers and deployers of in-scope AI systems should begin to evaluate the implications of this law now.

While an EU law, companies based in the US may not be able to ignore the AI Act given its broad scope. The AI Act will apply to in-scope AI systems (as defined in the AI Act) that are used in or produces an effect in the EU, regardless of where a company is established. Like the GDPR, many will recognize this extra-territorial effect. The AI Act establishes a regulatory scheme discrete and separate from other privacy laws, such as the GDPR, and may create competing obligations for compliance. Ultimately, the interplay of the AI Act with other privacy legislation remains an unresolved area.



At a high-level, the AI Act adopts a risk-based methodology to establish obligations for AI technologies. On one end of the spectrum, certain AI systems which pose unacceptable levels of risk will be banned under the current proposal. According to the proposal, this would include systems which provide real-time biometric identification. Other technologies that pose a high risk, such as those which affect safety and fundamental rights, will need to be assessed prior to commercialization of the technology as well as throughout the product's lifecycle. Requirements for high-risk tools may include the need to carry out mandatory rights impact assessments. Consumers will also have a right to receive explanations about decisions based on AI that affect their rights. Those systems presenting only a limited risk will still be subject to requirements, including certain transparency obligations.

For life sciences companies, the "high-risk" category of AI technologies may encompass many medical devices, including software as a medical device. High-risk AI systems include AI systems intended to be used as a safety component of a product and products covered by EU legislation listed in Annex II (which includes certain medical devices). Device manufacturers will want to keep an eye on the discussions around the AI Act as it would apply in addition to existing EU medical device regulations, and the requirements around data governance are likely to add additional elements to current compliance programs.

White House Executive Order on AI

In October 2023, the White House released an Executive Order ("EO") on the development and use of safe, secure, and trustworthy AI. The EO specifically sets forth

requirements for certain federal agencies as well as policies for AI development. The overall directives of the EO are likely to lend support to and boost the Food and Drug Administration's efforts to regulate AI in the life sciences industry. Amongst its top priorities is ensuring that privacy requirements and safeguards are met and implemented as AI technologies are developed and deployed. The order calls for NIST to create industry guidelines and best practices for deploying AI systems by the end of July 2024, including guidelines for AI developers as well as guidelines for assessing the safety and security of AI systems.

The EO also calls for bipartisan, comprehensive privacy legislation and underscores federal support for AI systems with privacy-preserving technologies. Agencies are directed to develop stronger cryptography protections as well as evaluate how such agencies collect and use commercially available information, especially personally identifiable information. Agencies are also required to develop guidelines for evaluating the efficacy of privacy-preserving techniques in AI technologies. The EO is likely to spur new privacy-related regulations and guidance from governmental agencies. Specifically, and of relevance to life sciences companies, the EO requires the Department of Health & Human Services ("HHS") to develop a strategy for regulating the use of AI in all phases of drug development as well as the implications of AI for device and drug safety more generally. Thus, life sciences companies utilizing or deploying AI may want to carefully evaluate the privacy implications and protections of their AI products.

Federal Trade Commission Guidance on AI Use and Claims

Part of the Federal Trade Commission's ("FTC") responsibilities includes enforcing consumer protection laws. Section 5 of the FTC Act broadly prohibits "unfair and deceptive acts or practices" in or affecting commerce. When it comes to the Agency's Section 5 authority and AI, the FTC has signaled that it is paying attention to the claims companies make about the use of AI in their products and services.

In February 2023, the FTC issued a blog post with guidance for companies making claims about its AI products. The FTC's guidance emphasizes the importance that products with AI claims work as advertised and that claims should not be false or unsubstantiated, including by exaggerating what an AI product can do or by promising an AI product can outperform a non-AI product. From a privacy perspective, companies will want to closely consider statements about the interplay between the collection and use of personal information and the development and/or deployment of AI. For example, life sciences companies developing AI tools or technology based on information they collect from study subjects should be mindful of the FTC's expectations around transparency. Further, any companies using AI tools as part of drug and device commercialization should consider its claims made in connection with any AI components of the products. Life sciences organizations should also be cognizant that predictive analyses issued in connection with the use of AI do not unfairly disadvantage certain persons and populations.

FTC guidance coupled with statements in recent enforcement actions make clear that the FTC has established itself as a key regulator of AI technologies. The agency is likely to provide additional guidance as AI products continue to evolve and proliferate in the upcoming year.

This authority has been bolstered by the fact that the FTC recently approved a resolution authorizing a compulsory process to issue civil investigative demands ("CIDs") in nonpublic investigations involving products and services that use or claim to be produced using AI or claim to detect the use of AI. The approval of this omnibus resolution is reflective of the current drive to inspect AI processes and the FTC's notable role in monitoring and enforcing AI development and claims.

2024 Outlook

As we look ahead to 2024, AI will continue to be top of mind for nearly every industry. In that same vein, policymakers and regulators are trying to keep pace with this technology's rapid adoption and deployment. In the absence of clear guidance and laws, life sciences companies may want to consider how to integrate an AI governance program into existing privacy programs and compliance efforts. By thinking about key privacy principles in the use and deployment of AI, such as notice, choice, and individuals rights (among others), companies may find themselves in a more agile position to shift with the evolving regulatory climate.

Pharma and Life Sciences Investigations and Prosecutions Update – December 2023

By: Joe Jay and Tom Reklaitis

False Claims Act Enforcement

According to the latest published figures, the Department of Justice ("DOJ") relies heavily upon the federal False Claims Act ("FCA") as a civil enforcement tool against fraud on federal health care programs. In its most recent publication, DOJ announced that it was a party to 351 FCA settlements and judgments during the prior fiscal year, the second-highest total for a single year since DOJ began tracking settlement figures.[1] Of the $2.2 billion in losses recovered, more than $1.7 billion was related to the health care industry.[2]

The DOJ continued to utilize the FCA as an enforcement tool against health care fraud schemes throughout FY 2023, as it entered into significant settlements with payors and providers alike. In December, DOJ entered into a $345 million settlement with Community Health Network, Inc. to resolve allegations that it violated the FCA by submitting claims to Medicare for unlawful referrals under the Stark law.[3] In September, the Cigna Group entered into a settlement to resolve allegations that it defrauded Medicare Advantage Plans by submitting inaccurate patient diagnosis data to increase payments.[4]

Criminal Prosecutions

In addition to the ongoing trend of entering into substantial settlements related to alleged FCA violations, the DOJ continue to pursue criminal prosecutions against corporate executives found to have defrauded federal health care programs during 2023. In November, a compliance officer at a pharmacy holding company was sentenced to 54 months in prison after being convicted of conspiracy to commit health care fraud and wire fraud for submitting claims to Medicare for medically unnecessary services.[5] In October, the DOJ announced charges against a former executive at a Medicare Advantage organization for allegedly submitting false and fraudulent claims.[6]

Other agencies have also added to the DOJ's health care fraud enforcement apparatus by bringing parallel or independent actions and investigations. For example, in December 2023, the Securities and Exchange Commission initiated an action against the CEO of a medical device startup while the U.S. Attorney's Office for the Southern District of New York brought a parallel prosecution for securities fraud.[7]

Corporate Integrity Agreements

The past year has marked a continuation of the decline in the number of Corporate Integrity Agreements ("CIAs") entered into by the Department of Health and Human Services Office of Inspector General ("HHS-OIG") to settle Federal healthcare investigation since 2020, with only 16 CIAs entered into.[8]

Department of Justice Initiatives/Enforcement Actions

By: Eve Costopoulos

I. Beginning in January 2023, the Department of Justice (DOJ) Criminal Division kicked off a number of initiatives that built upon prior years' expansion of policies relating to prosecution of corporate crime and the corresponding evaluation of corporate compliance programs. The DOJ Criminal Division rolled out i) a new Voluntary Self-Disclosure Policy for Business Organizations; ii) an updated Evaluation of Corporate Compliance Programs guidance; iii) a Pilot Program Regarding Compensation Incentives and Clawbacks; and iv) an approach to Compliance Officer accountability. These policies apply to cross-section of industries, including life sciences, and emphasize DOJ's belief that appropriately designed and comprehensive compliance programs are critical for the well-being of an organization.

In conjunction with these initiatives, DOJ also plans to add additional prosecutors to its staff who will be solely dedicated to investigating health care fraud.

A. Criminal Division Corporate Enforcement and Voluntary Self-Disclosure Policy (Self-Disclosure Policy)

In January, DOJ announced the Self-Disclosure Policy, which replaced the former FCPA Corporate Enforcement Policy which applies to FCPA cases as well as all other corporate criminal matters handled by the Criminal Division.[9] The policy is intended to incentivize early voluntary self-disclosure of potential wrongdoing by a company before an imminent threat of disclosure by a third-party. For a company to receive credit for self-disclosure of a criminal violation, the disclosure must:

- be made directly to the DOJ division to whom self-disclosure is sought.
- not be subject to any pre-existing obligation to disclose.
- be made "within a reasonably prompt time" after becoming aware of the misconduct.
- be prior to an "imminent threat" of disclosure or government investigation, and before the violation is publicly disclosed or otherwise known to the government.
- include all relevant facts concerning the misconduct known to the company, including identifying individuals who were involved in the misconduct.

If a company fully cooperates in an investigation, including the preservation, collection and production of relevant documents, as well as disgorgement and payment of restitution to victims, DOJ may reduce the penalties assessed to the disclosing company. DOJ's goal in increasing pressure on companies to self-disclose and cooperate is to build more effective cases against individuals. In the past, DOJ has emphasized that its "first priority in corporate criminal matters is to hold accountable the individuals who commit and profit from corporate crime."[10] To that end, the updated Self Disclosure policy does not include benefits for individuals.

B. Evaluation of Corporate Compliance Programs

Following up on the Self-Disclosure Policy, DOJ announced an updated Evaluation of Corporate Compliance Programs (ECCP) in March, which replaced its prior 2020 evaluation guidelines.[11] The ECCP is part of the continued development and enhancement of DOJ's compliance program evaluation guidelines and includes new guidance on i) the use of personal devices and communication channels at an organization and ii) compensation structures and consequences for misconduct. The ECCP clarifies the need for companies to develop strong compliance practices for the use of personal devices, communication platforms and messaging applications and to ensure that compensation plans drive compliance or disincentivize non-compliant behavior and misconduct.

1. **Personal Devices.** During an investigation, DOJ will now request data from mobile devices, including data from third-party messaging applications. If a company is unable to produce this data, DOJ prosecutors will investigate the company's ability or inability to access the data and whether the company's handling of the data complies with applicable privacy law. A company's cooperation with and ability to address this line of inquiry will impact any DOJ charging decision.

   Companies should ensure they have an effective compliance program applicable to personal devices and third-party messaging platforms, including policies for:

   - **Use of Electronic communication channels.** Use of all electronic communication channels employees, including the preservation or deletion settings available to each employee under each communication channel and procedures implemented to manage and preserve electronically communicated information.
   - **Data Preservation.** Preservation and accessibility of business-related data, including data contained within messaging platforms or stored on "bring your own devices", and preservation policies related to the transfer of data from personal phones or messaging applications to the company's systems.
   - **Risk management activities.** Assessments evaluating a company's business needs and risk profile and its control over business-related communication channels and evaluations of non-compliance and related impact on a company's compliance program, ability to conduct internal investigations, or ability to respond to government requests for information.

2. **Compensation Incentives and Claw Backs.** Compensation incentives for compliance and claw backs for compliance infractions have been integrated into DOJ enforcement activities for many years. In the ECCP, DOJ sets out the criteria by which it will assess a company's (i) compensation structures; (ii) disciplinary measures; and (iii) incentives to determine whether these programs promote compliant behavior and whether a company has adequate "consequence management" procedures to identify, investigate, discipline, and remediate violations of law.

   Compensation Structures and Disciplinary Measures. Prosecutors will evaluate a company's compensation structures and whether those structures foster a culture of compliance by considering:

   - **Policies.** Are there policies for recoupment or reduction in compensation for compliance violations or misconduct, including enforcement of clawback provisions to recoup previously awarded compensation in the event of corporate wrongdoing and deferral or escrow of certain compensation tied to conduct consistent with the company's values and policies.
   - **Disciplinary measures.** Does company publicize disciplinary actions, track data relating to disciplinary actions to measure the effectiveness of its consequence management program and monitor compliance-related allegations that are substantiated, and the effectiveness and consistency of disciplinary measures throughout the organization?
   - In assessing whether a company has effective incentives to promote compliant behavior, prosecutors will consider, among other things, whether a company has made compliance a means of career advancement, offered opportunities for management to serve as a compliance "champion," or made compliance a significant metric for management bonuses.

C. Pilot Program

The Pilot Program Regarding Compensation Incentives and Clawbacks (Pilot Program) became effective March 15, 2023 and will run through March 2026.[12] The Pilot Program has two parts:

- **Compliance Enhancements**. Every company that enters into a corporate resolution with the DOJ Criminal Division will be required to implement compliance-related criteria within its compensation and bonus systems and report annually to DOJ on the implementation. The criteria may include: (i) no bonuses for employees who do not satisfy compliance objectives; (ii) disciplinary measures for employees who violate law or for those who supervised employees who engaged in misconduct and knew of, or were willfully blind to, such misconduct; and (iii) incentives for employees who demonstrate a full commitment to compliance.
- **Deferred Fine Reduction**. Companies that seek to claw back compensation from corporate wrongdoers will be eligible for fine reductions in certain circumstances. DOJ may accord a fine reduction equal to the amount of any compensation that is recouped within the term of the resolution, as well as providing a fine reduction of up to 25% of the amount of compensation that was sought for good faith attempts to recoup compensation that are ultimately unsuccessful, provided that the company fully cooperates with DOJ, timely and appropriately remediates the misconduct, and initiates the claw back process by the time of the resolution of the matter.

D. Compliance Officer Liability

In a speech at New York University Law School in March 2022, Assistant Attorney General Kenneth Polite Jr. announced that prosecutors had been instructed to consider requiring chief executive officers and chief compliance officers (CCO) to certify that accuracy of annual reports submitted to the government and that their compliance program is reasonably designed and implemented prior to releasing the company from obligations under a resolution agreement.[13]

The first settlement requiring such a certification occurred in May 2022, when DOJ required a compliance officer of Glencore, a mining company, to provide a certification that the company has "met its compliance obligations pursuant to this agreement". This year, Gurbir Grewal, head of the U.S. Securities and Exchange Commission's Enforcement Division, spoke at the October 24, 2023 New York City Bar Compliance Institute meeting about more recent settlements and specifically addressed situations where compliance officers might be held individually liable for corporate wrongdoing. He reinforced that the SEC has no interest in pursuing compliance officers who act proactively and in good faith and indicated that enforcement actions would be brought against compliance officers only if i) they affirmatively participated in misconduct, ii) they misled regulators, or iii) they failed in carrying out their compliance responsibilities. He provided examples of instances where the SEC charged the CCO of the U.S. unit of LianLian for insider trading and misappropriation of material, nonpublic information about planned business acquisitions from the laptop of his girlfriend; where a CCO of an company deliberately prepared falsified compliance reports and provided them to the SEC during an investigation, and where a compliance officer adopted a handbook published by a professional organization instead of developing policies and procedures that were actually related to the firm's business or federal securities law and where the company did not conduct any compliance training or review of the compliance program.[14]

DOJ has indicated that this approach is intended to ensure that compliance officers are empowered, in the room where decisions are made, reporting directly to the board of directors about potential company violations and have the resources to prevent financial crime. Among the compliance community however, this policy appears punitive and aimed at imposing liability on compliance officers who try to do their best with limited resources.

While there have been no actions brought against compliance officers in the life sciences industry, we do believe that the SEC's actions in the financial services industry serve as a reminder to life sciences compliance officers that their company's compliance programs must be robust, proactive and tailored to appropriately address the business risks and that they must ensure that they are empowered, independent and authorized to act in the best interests of the organization.

II. Select DOJ Enforcement Actions

While the number of DOJ enforcement actions has continued to decline over past years, DOJ continues to remain focused on the provision of kickbacks by medical device companies to induce the prescribing activities of healthcare professionals, individual accountability of executive management for illegal behaviors, and the role of incentive compensation as an inducement for illegal conduct by contractors.

DePuy Synthes – DOJ announced that DePuy Synthes, a subsidiary of Johnson & Johnson, had agreed to pay $9.75 million to settle claims that it had violated the federal Anti-Kickback Statute and False Claims Act by providing approximately $100,000 in free products to a surgeon to perform operations outside the United States over the course of five years to induce a surgeon to use the manufacturer's products in surgeries performed in the U.S.[15] The lawsuit was originally filed under the *qui tam* provisions of the False Claims Act by a former sales representative.

Stimwave LLC – DOJ announced that Stimwave LLC, another medical device company, had agreed to pay $10 million and entered into a non- prosecution agreement to settle claims that it had conspired to violate the False Claims Act in connection with the design and manufacture of an implantable medical device that contained a non-functioning component that put patients at significant risk and had been marketed as a non-opioid alternative to chronic pain management.

The government was amenable to entering into the non-prosecution agreement based upon significant remedial actions taken by Stimwave, including replacing the management team under which the illegal activities had occurred, conducting an internal investigation into the misconduct of the prior management team, building out a compliance program in accordance with OIG guidelines, and cooperating with the DOJ investigation.[16]

The CEO of the company was indicted and charged with conspiracy to commit wire fraud and health care fraud. That prosecution is ongoing.[17]

Steven Donofrio – In May, Steven Donofrio was found guilty of conspiring to provide kickbacks in violation of the Anti-Kickback Statute and sentenced to 42 months in jail. The government alleged that Donofrio conspired with twelve other individuals to pay kickbacks in exchange for the referral of pharmacogenetic (PGx) tests, a type of genetic testing that identifies genetic variations that affect how an individual patient metabolizes certain drugs, to clinical laboratories in California. More than $28 million in illegal kickback payments were exchanged by those involved in the conspiracy.

In addition to Donofrio, ten defendants pleaded guilty prior to trial with three of them receiving federal prison sentences and another receiving probation.[18]

Genotox Laboratories Ltd. – In April, Genotox agreed to pay at least $5.9 million and enter into a five-year corporate integrity agreement to resolve a *qui tam* lawsuit alleging that it violated the False Claims Act by paying volume-based commissions to third party independent contractors in violation of the Anti-Kickback Statute and submitting claims to federal health care programs for unnecessary drug tests.[19] In parallel proceedings, the U.S. Attorney's Office for the Western District of Texas and Genotox entered into an eighteen-month Deferred Prosecution Agreement to resolve a criminal investigation regarding the same conduct.

Genotox admitted to paying kickbacks to independent contractor sales representatives and marketing firms ("Marketing Representatives") from revenue it received from billing Medicare and other federal government healthcare programs for lab testing orders that were facilitated or arranged for by the Marketing Representatives, in violation of the Anti-Kickback Statute. The laboratory tests were not covered and/or not reasonable and necessary, and Genotox admitted that it offered blanket orders and routine standing orders of drug testing for each provider to use for all patients in a provider's practice. These orders were generally at the highest reimbursement categories. As part of the settlement, Genotox admitted and accepted responsibility for paying kickbacks to the Marketing Representatives.

This settlement highlights the importance for life sciences companies that engage independent contractors to market products on a commission basis to ensure that there are specific compliance controls in place to monitor and assess their activities and to ensure that inappropriate behaviors, including the provision or receipt of kickbacks, are not being incentivized in an attempt to induce sales.

OPDP Year in Review

By: Dominick DiSabatino and Eve Costopoulos

Heading into 2023, we anxiously awaited FDA's Office of Prescription Drug Promotion's (OPDP) enforcement agenda, especially given that OPDP had not spoken for six months. Would OPDP kick-off a big 2023 by continuing to focus on the "low-hanging fruit" of product claims, singling-out the most noticeable violations that presented the greatest concern for public health? Would OPDP take another direction? As we all now know, nothing happened, and by Memorial Day Weekend, we were unsure if the lights were still on in Room 3203, Building 51.

Then, OPDP issued five enforcement letters[20] (four Untitled Letters and one Warning Letter) to pharmaceutical manufacturers during June – October, with two of the enforcement letters both issued on the same day on October 31st. While the five letters represented an increase over the four enforcement letters issued in 2022, there continues to be a downward trend in enforcement in recent years, with six enforcement letters issued by OPDP in each of 2021 and 2020 and ten issued in 2019.

FDA enforcement efforts on drug product claims and the broader agenda both appear to have been sharpened this year to pick at nuance, with the agency's focus on quantitative efficacy data and audience-appropriate presentation of the same, especially in direct-to-consumer (DTC) advertising, making it clear that so-called "consistent with label" messaging must be accompanied with the appropriate context as described by FDA in its 2018 CFL Guidance.[21] Especially as seen in OPDP's closing act on Halloween, OPDP reminded manufacturers in each of the two letters to think outside the box from various audience perspectives when developing promotional materials. OPDP doubled down on statements that were not, on their face, false or untrue, but rather potentially misleading depending upon the complexity of the information presented and the target audience for the information. OPDP telegraphed this, in part, in its October Brief Summary when it said "100% of OPDP employees recommend . . . reading the full [quantitative DTC communications guidance] guidance to learn more!"[22]

Is it safe to say that gone are the days of the OPDP layups? That firms need to think more critically about their promotional materials? The short answer is "no"—firms make mistakes and OPDP will correct egregious ones, but we're going to see less of those because industry has become more savvy over the past ten years or so. However, it does now appear that the scope of what is actionable from OPDP's perspective appears to have broadened because OPDP is looking more closely at product claims and the now myriad media channels delivering those claims to various audience. Below is the full list of takeaways from OPDP's activity in 2023 that should be incorporated into a company's approach to promotional materials in 2024, much of which you can read more about on our blog.

CFL Guidance. The CFL Guidance continues to remain relevant regarding what presentations may be considered "consistent" with FDA-Required labeling, including the adequacy of underlying substantiation and sufficiency of disclaimers and additional context. While FDA is open to the inclusion of information outside the label—as well as post-hoc analyses of clinical trial data itself—it is crucial that companies consider what additional context might be necessary to help consumers fully understand the claims, such as important limitations on how trial data is collected and analyzed.

Quantitative Information. Earlier in 2023, FDA finalized its guidance on Presenting Quantitative Efficacy and Risk Information in [DTC] Promotional Labeling and Advertisements (Quantitative

Guidance).[23] As described in our July blog post, this Quantitative Guidance explains that consumers are better at recalling and understanding quantitative descriptions and cautions firms from making efficacy claims in relative frequencies (i.e., statements like "33% reduction in symptoms" or "3 times as likely to experience a side effect") due to the increased risk of consumer misinterpretation. FDA recommends either not using relative frequencies at all or, at the very least, including corresponding data in absolute frequencies "prominently and in direct conjunction with the relative frequency measure." This was the issue addressed by OPDP in one of the Untitled Letters and the Warning Letter.

Review Process. A company's promotional review process is the key to minimizing the chances of receiving an Untitled or Warning Letter from OPDP. With respect to clinical data, we should expect that OPDP will analyze the data to determine whether they are sufficient to support the efficacy claims being made. So, now might be a good time to take a fresh look at promotional materials and the promotional review process, especially with the view to how the consumer may interpret the information being conveyed, whether that impression is supported by the data, and whether—per OPDP's preference—the material lays out in excruciating detail all the limitations, reservations, and other caveats that one might want to know when looking at the claim.

Efficacy Claims. Companies must be diligent and carefully review presentation of study data to ensure that it adequately substantiates efficacy claims and does not overstate the efficacy of the drug or creating a misleading impression of what patients may generally experience when taking the drug. FDA continues to reinforce its interest in assuring that efficacy claims are not misleading to either professionals or general consumers and has emphasized the so-called "factor 3" of FDA's CFL Guidance which requires companies to consider whether the communication "furnishes appropriate context." Companies should proceed with particular diligence and caution in making efficacy claims about a product that—while perhaps not supported directly with information contained within the four corners of the FDA-approved label—are nonetheless consistent with the label. Context is key—so the inquiry should take an honest, objective and inclusive look at what the audience need to know to ensure that the statement is fully appreciated with scientific context so as not to be even potentially misleading.

Audience. The type and extent of context necessary for efficacy claims may fluctuate depending on the intended audience. This is especially true when dealing with quantitative presentations of efficacy. One of the Untitled Letters signals that FDA is evaluating DTC communications from a simplified consumer lens, drawing conclusions from efficacy claims on their face and not assuming that consumers have a basic understanding of how clinical trials work. OPDP has made clear that the Quantitative Guidance is a priority for enforcement going forward. Companies should heed this warning and evaluate whether their claims are in line with the Quantitative Guidance recommendations.

Risk Information. Boxed warnings and/or contraindications should always be prominently displayed in promotional materials. For products with boxed warnings, companies should assess the inclusion and placement of general side effect statements and whether their content or placement may appear to negate or minimize any serious and potentially life-threatening risks associated with the drug.

Social Media. OPDP is closely monitoring promotional advertising on social media. It is critical that companies ensure that any social media promotion, along with all promotional materials, is appropriately reviewed through a company's internal review process and submitted to FDA on FDA Form 2253.

KEEP YOUR EYE ON

Challenges to *Chevron*

By: Eve Costopoulos

As we all know, for its 2023-2024 term, the Supreme Court agreed to hear several cases that could potentially lead to the further limitation or demise of the *Chevron* doctrine, first articulated by the Court in *Chevron U.S.A., Inc. v. National Resources Defense Council, Inc*. in 1984. That ruling allows lower courts to defer to a federal agency's interpretation of a statute that is either silent or ambiguous on a particular matter, as long as the agency's interpretation is reasonable. In *Chevron*, the Court established a two-part test to determine whether a federal agency has reasonably interpreted a statute in support of a regulation, and if it has, a court must defer to the agency's interpretation.[24] In recent years, the Court has been critical of the doctrine and has circumscribed its application in a number of cases, including in *West Virginia v. EPA*, where it restricted EPA's ability to limit greenhouse gas emissions, using the "major question" doctrine – that requires an agency to point to clear statutory authorization before it can step into cases raising issues of vast "economic and political significance".[25]

On January 17, the Court heard arguments in two cases that provide it with another opportunity to further limit the scope of deference to federal agency authority. In both *Loper Bright Enterprises v. Raimondo*[26] *and Relentless, Inc. v. Department of Commerce*[27], *plaintiffs challenged a federal regulation issued by the National Marine Fisheries Service that requires herring fishing boat operators to pay the salaries of government monitors who ride aboard fishing vessels to conduct federally required compliance checks. Applying the Chevron* doctrine, the lower courts (the D.C. and First Circuits) had upheld the regulation, finding that it was a reasonable interpretation of the law by the regulatory agency and thus entitled to deference.

During the hearing before the Court, the fishing companies argued that the regulation was invalid, because the law does not explicitly state that fishing boat operators must pay the salaries of monitors in these circumstances. Further, plaintiff's attorneys argued that application of the *Chevron* doctrine in these cases worked to prevent a court from actually interpreting the law, which is within their jurisdiction. Arguing for the plaintiff Loper Bright Enterprises, Paul Clement characterized the *Chevron* doctrine as ambiguous and resulting in real world costs for small businesses and he argued that courts should be allowed to interpret the meaning of laws, rather than regulatory agencies. U.S. Solicitor General Elizabeth Prelogar argued that overturning *Chevron* would open the floodgates to lawsuits seeking to overturn prior decisions that were based upon it, where the courts gave deference to an agency's reading of a law, whether or not they agreed with that interpretation. Rather than overrule *Chevron*, Prelogar suggested that the Court could clarify its limits.

Courtroom observers noted that all the Justices were engaged in the discussions that occurred during the three-and-a-half-hour argument. Justice Gorsuch noted that the application of *Chevron* almost always works against small business, while Chief Justice Roberts surmised that the impact of overturning *Chevron* could be minimal with respect to prior cases that relied on it. The liberal justices appeared to support the continued existence of *Chevron*, with Justice Kagan noting that federal agencies have the technical expertise and capabilities to resolve ambiguities in laws and Justice Jackson supporting an agency's ability to make policy under *Chevron*.

While having little to do with health care on its face, a ruling overturning or further limiting *Chevron* would significantly impact the workings of federal agencies, including those that regulate food and drugs, and could take the determination of health care policies and associated technical regulatory decisions out of the hands of administrative agencies and place them in the jurisdiction of the courts.

Federal Antitrust Enforcement Activity Promoting Generic and Biosimilar Competition

By: Bevin Newman and Cortney Inman

The life sciences and healthcare industries remain among the top enforcement priorities of the federal antitrust agencies with these industries having accounted for roughly 40 percent of enforcement activity by the Federal Trade Commission (FTC) and Department of Justice, Antitrust Division (DOJ) in FY 2022.[28] The FTC in particular has reinvigorated its focus on promoting and protecting generic drug and biosimilar competition and can be expected to pursue enforcement actions against perceived abuses of Orange Book patent listings under the federal antitrust laws, as well as challenging transactions it perceives shield brand drugs from competition.

The FTC has long expressed concerns about the impact of the Orange Book patent listing process on generic competition. The FTC has characterized improperly listed patents as an abuse of the regulatory system that creates an artificial barrier to entry and prevents lower cost drug alternatives from entering the market, hindering competitive drug pricing and harming the consumer and healthcare system as a whole. The FTC also asserts that the specter of infringement suits by brand drug manufacturers may chill investment in particular therapies.

The FDA's Orange Book lists all approved drug products, and includes, among other things, information relating to a product's patent and exclusivity protections. Under the Hatch-Waxman Amendments to the federal Food, Drug, and Cosmetic Act (FDCA), all New Drug Application (NDA) applicants must submit certain information concerning patents that claim either the drug itself—i.e., a drug substance (active ingredient) patent or drug product (formulation or composition) patent— or a method of using the drug. Upon approval, FDA includes such patent information in the Orange Book listing for the drug. Importantly, FDA views its role in the patent listing process as ministerial, meaning it does not evaluate whether the submitted patents meet the statutorily defined criteria. The Orange Book puts generic companies on notice of patent protections for brand drugs. Generic companies seeking to file an Abbreviated New Drug Application (ANDA) must include within their application certifications relating to the patent protections of the brand drug. If a brand company timely sues a generic competitor for infringement of an Orange Book listed patent, this triggers an automatic statutory bar on the FDA's approval the generic drug for up to 30 months.

In September 2023, the FTC issued a Policy Statement (supported and endorsed by the FDA) on *Brand Pharmaceutical Manufacturers' Improper Listing of Patents in Orange Book*[29] warning pharmaceutical companies that they could face legal action if they improperly list patents in the Orange Book and outlined a number of potential enforcement methods for combatting these perceived harms, including:

- Challenging improper patent listing as unfair competition in violation of Section 5 of the FTC Act;
- Challenging improper patent listing under a monopolization theory;
- Closely scrutinizing "a firm's history of improperly listing patents during merger review;" and
- Potential referral to DOJ for criminal action against the individuals responsible for the certification of improper patent listings.

In November 2023, the FTC issued notice letters to a number of brand drug manufacturers challenging more than 100 patents held by manufacturers of brand-name drugs and drug products as improperly or inaccurately listed in the Orange Book.[30] The Commission also notified FDA that it disputes the accuracy or relevance of the listed information for these patents, which may require that the manufacturers remove the listing or certify under penalty of perjury that the listings comply with applicable statutory and regulatory requirements.

While the FTC utilized the FDA's patent listing dispute process to address the patents—a process open to any interested person for disputing the accuracy or relevance of patent information published in the Orange Book—the FTC's letters to the drug companies highlight that the Commission retains the right to take any further action as needed in the public interest, which includes investigating the manufacturers' conduct as a violation of the antitrust laws.

Later in November, the FTC filed an amicus brief in the matter of *Mylan Pharmaceuticals v. Sanofi-Aventis US*, in which the defendant has moved to dismiss the complaint alleging that it has monopolized the market for an injectable insulin product in part by abusing the Orange Book listing mechanism.[31] The FTC took no position on the specific factual allegations in the case, but used the brief to reiterate its position that improper Orange Book listings like those alleged in the case can cause significant harm to competition, and that "improperly listing a patent in the Orange Book can constitute illegal monopolization or part of an illegal course of monopolistic conduct under Section 2 of the Sherman Act." – This is further indication that the FTC is preparing to pursue enforcement activity against perceived abuses of Orange Book listings under the federal antitrust laws.

Amgen Inc. v. Sanofi: How the Supreme Court's Recent Decision Impacts Patents in Life Sciences

By: Lorna Tanner, Nathan Lee and Juaniece Rainey

For the first time in decades, the U.S. Supreme Court addressed the enablement requirement[32] for patents in *Amgen Inc. v. Sanofi*, on May 18, 2023. The case concerned a dispute among Amgen and Sanofi over patents for LDL cholesterol-reducing drugs, which are antibodies that bind to and inhibit PCSK9—a protein that binds to and degrades LDL receptors responsible for extracting LDL cholesterol from the bloodstream.[33]

In 2014, Amgen brought suit against Sanofi, asserting that Sanofi's biologic drug Praluent® (alirocumab) infringed Amgen's patents. Amgen's patents, covering Amgen's biologic drug Repatha® (evolocumab), claimed antibodies that (1) "bind to specific amino acid residues on PCSK9," and (2) "block PCSK9 from binding to [LDL receptors]."[34] Sanofi argued that Amgen's claims were invalid for lack of enablement because Amgen sought to claim potentially millions of antibodies that can perform two functions (i.e., binding to and blocking PCSK9), while disclosing only 26 exemplary antibodies in the specification that perform the two functions. Amgen argued that, in addition to the specific 26 exemplary antibodies, they provided two alternative methods for reaching at the entire genus of antibodies with sufficient details, thus enabling a person of ordinary skill in the art to make and use the claimed genus of antibodies.

In a 9-0 unanimous decision, the Supreme Court affirmed that Amgen's patents were invalid for lack of enablement, stating that the claims described little more than a "research assignment."[35] The Court held that a patent claiming an entire class of processes, machines, manufactures, or compositions of matter must teach those skilled in the art to "make and use the entire class," while noting that the "specification may call for a reasonable amount of experimentation to make and use a patented invention."[36] And the Court said that Amgen's patents – containing more than 400 pages of disclosure – did not provide enough to do so.

Post Amgen

Being a rare Supreme Court decision about the enablement requirement, the ruling in the *Amgen Inc. v. Sanofi* case will have wide implications to life science companies' patent strategies. While the full impact of the ruling is still to be seen, the decision is being widely cited in courts at different levels to determine validity of patents in life sciences. For example, this September, in the *Baxalta Inc. v. Genentech, Inc.*[37] case, the Federal Circuit affirmed invalidity of Baxalta's patent claim that "covers all antibodies that (1) bind to Factor IX/IXA; and (2) increase the procoagulant activity of Factor IXa,"[38] saying that it is "indistinguishable from [*Amgen*]."[39]

The ruling will likely make it more difficult for companies to obtain patents for broad classes of inventions, including and especially biologics claimed by function alone. For example, in a patent appeal case decided in December, the Patent Trial and Appeal Board (PTAB) held claims directed to vaccination with "mRNA encoding a coronaviruses spike protein" not enabled, saying that it is "similar to the facts in Amgen."[40] Repercussions will also likely be felt outside of biological patents. In a patent application appeal,[41] PTAB, citing *Amgen*, held claims directed to a conductive polymer

defined by its structure not enabled, where the claims recited that "R is any substituent" and no upper limit for number of repeating units were provided. This decision could be relevant to small molecule patents, insofar as the compounds are claimed as a genus with broadly defined substituents.

Further, *Amgen* may affect the decision on how/when/whether to file a patent application. For example, to seek broader protection for the invention, one may want to generate more data, possibly leading to more time and money needed before the filing of the patent application.

Takeaways

The Supreme Court's ruling emphasized that a patent must teach those skilled in the art to "make and use the entire class" of inventions, and that the specification may call for a reasonable amount of experimentation to make and use a patented invention but not undue experimentation.[42] Still it may not be clear how much disclosure and guidance is needed to "make and use the entire class" of inventions, patent holders and applicants can benefit from providing more guidance and specific examples of the claimed invention.

Patent applicants should consider including claims with varying scopes in patent applications, from broader genus claims to narrower species claims, such that narrower claims can survive and protect the core invention, even if broader claims are invalidated for lack of enablement. Further, patent holders should consider keeping patent families pending by filing continuing applications, to allow additional opportunities to file claims with different scope when needed.

On the other hand, parties seeking to invalidate an existing patent, can consider attacking genus claims or claims defined functionally, even if some guidance and examples are provided in the specification. A patent claim can still be invalidated as far as the court finds that the disclosure is not enough to "make and use the entire class" of inventions, as the Supreme Court did in *Amgen*, where the patents had the specification with more than 400 pages.

FDA's Proposed Rule on LDT Regulation and the Debate over Agency Deference

By: Scott Liebman and Audrey Crowell

In October of this year, the Food and Drug Administration ("FDA" or "the Agency") issued a highly anticipated proposed rule outlining the regulatory framework and implementation plan for Laboratory Developed Tests ("LDTs").[43] This rule, if finalized, could have a significant impact on the operations of LDT manufacturers, as LDTs have historically been a product category for which FDA has exercised enforcement discretion.

Unsurprisingly, the proposed rule has received considerable pushback and has garnered more than six thousand official comments.[44] Many industry participants, including the American Clinical Laboratory Association (the "ACLA") claim that FDA's interpretation of the Food, Drug, and Cosmetics Act ("FDCA") is overly expansive and that the Agency does not, in fact, have the authority to regulate lab-developed diagnostic products in the absence of a specific grant from Congress.[45] Although this argument is a common response to any FDA rule that purports to increase regulation, the argument might cut deeper, as the Supreme Court is set to hear a case challenging the long-established Chevron doctrine (the "Chevron Doctrine") – a judicial policy under which executive agencies (*e.g.*, FDA) are afforded deference in their interpretations of ambiguous legislation.

For FDA, though, the proposed rule appears to be more about health and human safety than flexing its rulemaking power. LDTs have evolved in the nearly fifty years since they burst onto the scene, now used quite often in clinical decision-making and for the selection of therapeutic options for serious diseases. Congress has not been able to pass legislation, and yet technology propels forward—technology that, according to FDA, "[has] a significant impact on public health."[46]

I. The Proposed New Rule

A. Overview

On October 3, 2023, FDA issued a proposed rule that, once finalized, would (i) codify the Agency's long-standing position that In Vitro Diagnostics ("IVDs"),[47] including LDTs are subject to regulation as "devices" under the FDCA, and (ii) phase-out FDA's historical enforcement discretion with respect to LDTs.

B. Background

1. FDA's Historical Regulatory Approach for LDTs

The regulatory framework for medical devices was established under the Medical Device Amendments of 1976, and FDA has long interpreted the statutory definition of "device"[48] to include IVDs. Although LDTs are a subset of IVDs, technically making them a device subject to FDA regulation under FDA's interpretation, FDA has historically implemented a policy of so-called "enforcement discretion" for LDTs because, at the time of the device amendments nearly fifty years ago, FDA considered LDTs simple tests that posed little risk to patient safety – they were made and intended for use in a single clinical laboratory for a small volume of patients. Because of FDA's policy of enforcement discretion, LDT manufacturers have not been required to comply with registration requirements, premarket review, "Quality System" regulation, and other regulatory requirements applicable to regulated devices. However, despite the official policy of enforcement discretion, FDA has always claimed that it maintains the authority to regulate LDTs and intends to do so when such products pose a threat to public health and safety.

Over the past decade, as clinical laboratories and diagnostic testing have become more sophisticated, FDA has expressed its intent to begin regulating LDTs, giving significant focus to certain categories of LDTs that it deems high-risk (*e.g.*, direct-to-consumer LDTs). In 2014, FDA issued a draft guidance that would have established a regulatory framework for LDTs, including a phase-out of its enforcement discretion policy.[49] However, the guidance was never finalized due, in large part, to concern from laboratories and other industry participants over FDA's authority to implement such a framework. Subsequently, in 2017, FDA issued a Discussion Paper on LDT Policymaking, notably stating that the Agency would not be finalizing its 2014 draft guidance, in order to allow Congress time to "develop a legislative solution."[50] In the discussion paper, FDA again asserted its position that LDTs fall within FDA's regulatory authority, but requested that Congress weigh in to confirm FDA's interpretation of its authority. After years of discussions over potential regulatory approaches for LDTs between FDA and the industry, all eyes were on Congress for a final solution.

2. Legislative Efforts

The first legislative proposal to overhaul the diagnostic testing space was the Diagnostic Accuracy and Innovation Act (DAIA), which was issued as a discussion draft in 2017 but did not gain much traction.[51] Subsequently, the Verifying Leading Edge IVCT Development (VALID) Act was introduced and ultimately considered as part of the Senate proposals for the new user fee reauthorization in 2022.[52] This legislation would have adopted a new category of FDA-regulated products, called In Vitro Clinical Tests (IVCTs), which would encompass both IVDs, generally, and LDTs, specifically. Under the legislation, FDA would have been required to establish new regulatory frameworks specifically for IVCTs. However, the legislation was ultimately not passed.

Although FDA has been clear that its preferred approach for regulating diagnostic products, specifically LDTs, would be to act according to a Congressionally-developed statutory framework, FDA has also been clear that action is needed to ensure patient safety in the face of increasingly sophisticated, and increasingly underperforming, LDTs. Therefore, FDA has taken administrative action through the proposed new rule.[53]

C. Key Provisions of the Proposed Rule

The proposed rule, if finalized, would do two important things – (1) amend the regulatory definition of "IVD Products" and (2) phase out FDA's policy of enforcement discretion for LDTs.

1. Redefining "IVD"

The first notable piece of FDA's proposed new rule is the amendment to the regulatory definition of IVD, which would add the following clause to the second sentence of the regulatory definition as follows: "These products are devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the act), and may also be biological products subject to section 351 of the Public Health Service Act, **including when the manufacturer of these products is a laboratory**" (emphasis added). FDA has long held the position that all IVDs (including LDTs) are devices under the FDCA but the proposed amendment would codify this interpretation in the form of a more permanent regulation through the notice-and-comment rulemaking process.

2. Phasing Out Enforcement Direction for IVDs

Importantly, the proposed rule, if finalized, would also introduce a phased approach to ending FDA's policy of enforcement discretion for LDTs. The phased approach would establish timelines for LDT sponsors to comply with different categories of FDA device regulations, and the clock would start with the publication of the final rule, which would confirm the final phase-out policy, and be the date to which all five phases would be anchored. The proposed phases are as follows:

Stage 1:

LDTs are subject to Medical Device Reporting (MDR),[54] as well as adverse event reporting,[55] **one year** after publication of the final rule;

Stage 2:

LDTs are subject to registration/listing,[56] labeling,[57] and investigational use[58] requirements **two years** after publication of the final rule;

Stage 3:

LDTS are subject to Quality System Regulations (QSR)[59] **three years** after publication of the final rule;

Stage 4:

High-risk LDTS are subject to premarket review[60] **three-and-a-half years** after publication of the final rule; and

Stage 5:

Mid- and low-risk LDTs are subject to premarket review[61] **four years** after publication of the final rule.

3. Request for Comments on Potential Exclusions

The proposed rule includes several specific requests for comments, which focus primarily on potential exceptions to the phaseout policy (*i.e.*, areas in which FDA should continue to exercise enforcement discretion). Although the proposed rule does not provide a specific stance on the following topics, it opens the door for a dialogue between FDA and the industry, signaling that the Agency may be open to continuing its policy of enforcement discretion in one or more of these areas, as long as the policy can be structured in a way that does not jeopardize patient safety: (a) "grandfathering" in (*i.e.*, continuing a policy of enforcement discretion with respect to premarket review and Quality System requirements for) currently marketed LDTs; (b) exclusions for Academic Medical Centers ("AMCs"); and (c) coordinating with other state- and federal-level accreditation and oversight programs.

II. 2024 Outlook

In the proposed rule, FDA spends a full fifteen pages justifying its initiative to clarify the regulatory ambiguity surrounding LDTs, which appears to be largely driven by the slew of safety and efficacy concerns that arose out of the COVID-19 pandemic, when FDA was unable to regulate products in its usual manner. As more and more reports of dangerously underperforming LDTs come to light, LDT instrumentation and software become increasingly complex, and LDTs are more commonly being used to inform clinical decision-making, as well as to screen, predict, diagnose, and even recommend treatment options for serious diseases, a perfect storm is brewing that poses a real threat to patient safety and, in the eyes of FDA and supporters of the proposed rule, calls for a timely correction of this significant regulatory blind spot.

Despite the valid rationale behind FDA's focus on increasing LDT regulation and support from heavy-hitting industry groups, like AdvaMed,[62] legal challenges to the final rule are expected, as other industry participants have been publicly critical of the proposed regulatory scheme, many arguing that the Agency has interpreted the FDCA in a manner that exceeds the authority that the statute actually grants. For example, the ACLA voiced its opposition to the proposed rule before even submitting an official comment, stating that "ACLA has long taken the position that FDA does not have statutory authority to regulate LDTs under its medical device authority and strongly opposes unilateral action that exceeds the Agency's current authority."[63]

In terms of timing, FDA's Center for Devices and Radiological Health ("CDER") is currently set to follow up with a final rule in April 2024 – just a handful of months from now. Although FDA declined requests to extend the 60-day comment period,[64] indicating that the Agency could be quite serious about expediting a final rule for LDT regulation, many are skeptical that FDA will actually be able to issue a final rule in this short timeframe. For example, many of the notable final rules issued by CDER in the past decade were published a full three to four years, not months, after their proposed rules. Additionally CDER looks to be busy regulating other important device categories, such as the burgeoning digital health space, and is scheduled to issue almost twenty major policies this year alone.[65] Although these factors appear to make it unlikely that FDA will be able to mobilize a final rule as soon as this spring, industry participants should prepare for the possibility that the Agency chooses to prioritize and expedite the final rule.

In the meantime, manufacturers of LDT products should prepare for compliance with the impending final rule by prioritizing compliance initiatives based on the staged approach established in the proposed rule, beginning with Stage 1 reporting requirements. Manufacturers of LDT products that involve complex and/or automated software and LDT products that test for serious diseases, such as cancer and heart disease, should be especially vigilant, as they may be the target of initial enforcement actions following FDA's final rule.

KEEP YOUR EYE ON

Efforts to Control Drug Prices

By: Bevin Newman, Eve Costopoulos, Audrey Crowell and Yang Li, Ph.D.

Last year, Medicare was, for the first time, granted the authority to directly negotiate the price of certain high-expenditure, single-source, prescription drugs as part of the Inflation Reduction Act – a law aimed at expanding access to Medicare benefits, which includes lowering the cost of Medicare Part D ("Part D") drugs.[66] In August 2023, the Biden Administration announced the first ten medicines that would be subject to price negotiations, with the goal of reducing drug spending by the federal government and, in turn, cost to Medicare beneficiaries. These ten medications include drugs that treat diabetes, strokes and heart failure, cancers, arthritis, and other conditions, and which cost Medicare billions of dollars annually. The drugs were chosen through a process that prioritized those that account for the highest Medicare spending, have been on the market for years, and do not yet face competition. The final negotiated prices will be announced in September 2024 and will become effective in 2026. Additional drugs will be selected in coming years and the Congressional Budget Office estimates that the price reductions could save the federal government as much as $100 billion by 2031.[67]

Even though they have signed agreements to negotiate prices with Medicare, at least nine pharmaceutical manufacturers, as well as PhRMA and the U.S. Chamber of Commerce, have filed lawsuits against the Department of Health and Human Services ("HHS") over the Drug Price Negotiation Program in six federal courts, with more suits expected to follow.[68] The manufacturers allege that the price negotiations are unconstitutional, violating the First (freedom of speech), Fifth (taking of private property for public use without just compensation), and Eighth (imposition of excessive fines) amendments of the Constitution, and that HHS circumvented the requirements of the Administrative Procedure Act by implementing the Drug Price Negotiation Program through guidance rather than the formal regulatory process. Manufacturers believe that the program will squander innovation for lifesaving therapeutics by diminishing profits and, thus, leading to reductions in the development of new and innovative drugs, especially for conditions affecting vulnerable populations like the elderly. Further, PhRMA has pointed out that the Drug Price Negotiation Program ignores the role of Pharmacy Benefit Managers ("PBMs") and insurers in determining patient out-of-pocket costs for patients, and industry participants like Eli Lily have expressed their concerns that the program will essentially create "winners" and "losers" among patients in terms of drug access.

Although it looks like HHS is poised to take full advantage of its new authority to regulate certain prescription drug prices, all eyes will certainly be on the courts as industry challenges could significantly change the scope of HHS' new Drug Price Negotiation Program. Furthermore, the administration has at the same time set its sights on PBMs' role in determining the cost of prescription drugs to patients. Beginning in 2021, the Federal Trade Commission (FTC) issued a report to Congress suggesting that it could investigate or challenge so-called rebate walls due to their potential to create or maintain the market power of pharmaceutical products on a PBM's formulary to the disadvantage of lower-cost or higher-quality alternatives that become available.[69] The FTC followed the report in 2022 by launching expansive study aimed at shedding light on several PBM practices, including negotiating rebates and fees with drug manufacturers that may skew the formulary incentives and impact the costs of prescription drugs to payers and patients.[70] The study, targeting the six largest PBMs in the U.S. grew in 2023 to include additional targets.[71] While no report or enforcement activity has come from the study, in July 2023 the FTC withdrew all of its previous advocacy statements and studies related to PBMs that opposed mandatory PBM transparency and disclosure requirements.[72] The FTC warned against reliance on the Commission's prior conclusions given the agency's ongoing study of the PBM industry's practices. In tandem with its efforts in the Drug Price Negotiation Program, we expect that the Administration will continue to assess and evaluate PBM practices and their impact on pricing.

And in December 2023, further efforts by the administration to promote competition in healthcare and to lower prescription drug costs resulted in the publication of a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights ("Draft Guidance") for deciding whether the Government may exercise "march-in" rights and take a pharmaceutical company's drug patents developed with federal funds and share them with other companies. These controversial "march-in" rights have rarely, if ever, been exercised since its initial creation by the Bayh-Dole Act of 1980.

The newly announced Draft Guidance lists numerous factors and considerations for evaluating whether the Government should exercise the "march in" rights. Many of them appear to direct government agencies to consider specifically the price of prescription drugs:

- "Has the contractor or licensee made the product available only to a narrow set of consumers or customers because of high pricing or other extenuating factors?"
- "Is the contractor or the licensee exploiting a health or safety need in order to set a product price that is extreme and unjustified given the totality of circumstances?"
- "[H]as the contractor or licensee implemented a sudden, steep price increase in response to a disaster that is putting people's health at risk?"
- "At what price would another licensee(s) be able to make the product available to the public?"

It is also interesting to note that the Draft Guidance appears to recognize that the FDA's regulatory exclusivity is not subject to the "march-in" rights. The Draft Guidance asks agencies to consider if "the product or service [is] subject to regulatory exclusivity, such as those provided by the FDA," and "how much time remains in the period of exclusivity."

In an initial response to the administration's proposed use of "march-in" rights, Pharmaceutical Research and Manufacturers of America (PhRMA) warns that misuse of these rights would chill innovation and undermine collaboration between the public and private sectors, and that promising new technologies would sit on the shelf benefitting no one. The Draft Guidance is currently open to public comment for 60 days.

We expect that the administration's diverse efforts to try to get a handle of and control over drug prices will continue to play out in challenges involving manufacturers, PBMs and other parties that have a hand in the pricing of drugs.

340B: A Shifting Landscape

By: Erica Kraus and Arushi Pandya

Although in place for over thirty years, the 340B Drug Pricing Program (the "340B Program" or "Program") continues to evolve. Recent court decisions and the response of regulators and industry have hastened the rate of change to the Program, and 2023 has seen pharmaceutical companies and 340B entities significantly recalibrating their relationships as a result. We expect continued evolution of these relationships over the upcoming year.

The 340B Program

The 340B Program is a federal program administered by Health Resource Services Administration ("HRSA"), which requires drug manufacturers that participate in the Medicaid drug rebate program to provide covered outpatient drugs to enrolled covered entities at or below a statutorily defined ceiling price.[73] Covered entities include hospitals and certain other entities, such as federally qualified health centers, that meet eligibility requirements related to payor mix and serve low-income and rural patients. Covered entities may only provide drugs through the 340B Program to eligible patients, and can generate revenue based upon the difference between the 340B Program price and insurance reimbursement rates. Pharmaceutical manufacturers sell 340B Program drugs to wholesalers, which then distribute them to covered entities and their contract pharmacies (which dispense the drugs on behalf of covered entities).

340B Program Litigation

The 340B Program has been shaped by a series of notable court cases. The landscape of the 340B Program shifted dramatically in 2015 when the D.C. District Court ruled that the Department of Health and Human Services ("HHS") did not have broad rulemaking authority, and instead only had limited rulemaking authority for certain discrete aspects of the 340B Program.[74] As a result of the ruling, HRSA retracted a "mega-reg" intended to provide significant guidance to the industry on the specifics of the Program, and has pulled back on other efforts to issue regulations on the scope of the 340B Program and enforce related rules.

Contract Pharmacy Restrictions

During the early years of the 340B Program, HHS issued guidance stating covered entities could each use one contract pharmacy to distribute 340B Program drugs, because few covered entities had pharmacies in-house.[75] In 2010, HHS provided additional flexibilities and issued guidance stating covered entities could use an unlimited number of contract pharmacies.[76] Beginning in 2020, pharmaceutical manufacturers increasingly began to impose requirements on the distribution of 340B drugs, in particular by disallowing 340B pricing for drugs dispensed at contract pharmacies (as opposed to at a covered entity's in-house pharmacy), or limiting the number of contract pharmacies at which 340B pricing would be allowed or the circumstances under which 340B pricing would be

allowed at contract pharmacies. Some pharmaceutical manufacturers also imposed new or increased data-sharing requirements, including for claims information, for covered entities.

After HRSA sent enforcement letters to manufacturers informing them that such policies violated the requirements of the 340B Program and issued an Advisory Opinion stating the 340B Statute requires manufacturers to deliver 340B Program drugs to an unlimited number of contract pharmacies, manufacturers brought lawsuits challenging HRSA's enforcement actions and alleging HRSA had exceeded its enforcement authority. These legal challenges resulted in incongruent decisions from trial courts, with one court siding with manufacturers and another with HRSA. In 2023, the first appellate court to consider the issue ruled against HRSA and found manufacturers are not required to offer 340B Program pricing to an unlimited number of contract pharmacies.[77] The Third Circuit in that case found that because the statutory language and structure of the 340B Statute does not explicitly or implicitly require that manufacturers deliver drugs to an unlimited number of contract pharmacies, manufacturers' restrictions on delivery to contract pharmacies did not violate the 340B Statute, and HRSA's violation letters and Advisory Opinion were unlawful. The court did not opine on whether a minimum number of contract pharmacies could be used by covered entities. Cases are still pending in the U.S. Court of Appeals for the Seventh Circuit and the U.S. Court of Appeals for the D.C. Circuit, which may result in a circuit split. In light of the Third Circuit's decision, pharmaceutical manufacturers have continued to impose restrictions on 340B pricing for drugs not dispensed at a covered entity's in-house pharmacy.

Definition of Eligible Patient

More recently, covered entities have sought ways to leverage judicial limitations on HRSA rule-making authority. In November 2023, a South Carolina District Court struck down HHS' narrow definition of a "patient" eligible to receive a 340B drug, and instead ruled in favor of covered entities by endorsing an expansive view of who may be considered a "patient."[78] Under the 340B Statute, a covered entity may only resell or transfer a 340B drug to a person who is a "patient" of the entity, but the 340B Statute does not define "patient." In 1996, HRSA issued guidance that stated an individual is a "patient" if (i) the covered entity has established a treatment relationship with the individual such that the entity maintains records of the individual's health care; (ii) services are received from a health care professional who is employed by or under contract with the entity such that the entity is responsible for the care provided; and (iii) the services are consistent with the range of services for which grant funding or FQHC-look alike status has been provided.[79] HRSA conducted an audit of Genesis Health Care ("Genesis") in 2017 and ultimately determined that Genesis failed to maintain auditable program records and had dispensed 340B drugs to individuals who were not "patients", which resulted in Genesis' removal from the 340B Program. In 2019, HRSA issued a letter to Genesis that stated a covered entity must have initiated the health care service resulting in the prescription. Subsequently, Genesis brought suit regarding HRSA's interpretation of "patient" in its letter. The court determined HRSA's definition of "patient" in the 2019 letter and its 1996 guidance conflicted with the plain language of the 340B Statute, as the lack of definition suggested an ordinary meaning. Additionally, the court determined HRSA's interpretation was contrary to the purpose of the 340B Statute, which is designed to make covered entities profitable, which purpose suggests a broader definition of "patient."

HHS is likely to appeal the ruling, and the outcome of the case has significant implications for covered entities and pharmaceutical manufacturers alike. The court's decision emphasizes the substantial limitations on HRSA's ability to enact or enforce rules related to the 340B Program that may be more specific than and arguably conflict with the plain, but broad, language and intent of the statute. On the other hand, the court limited its relief to Genesis and also found HRSA possesses authority to implement its interpretations of "patient" under the Program's administrative dispute resolution process. While the broad definition of "patient" accepted by the court has the potential to benefit covered entities by expanding 340B pricing access, such access may continue to be curtailed by pharmaceutical manufacturer restrictions that HRSA has little ability to curb.

State Response

States have also entered the 340B Program arena, and in 2023, a handful of states enacted and proposed laws disallowing manufacturer restrictions on 340B pricing access, forbidding "clawback" provisions that prohibit pharmacy benefit managers ("PBMs") from recouping a drug's reimbursement amount, and limiting covered entity data-sharing requirements, such as Louisiana's prohibition on requiring or compelling the submission of pricing data pertaining to 340B drugs to third-party payors.[80] On the other hand, in light of rising health care costs and to promote transparency, some states have created their

own new reporting requirements for covered entities. For example, Maine enacted requirements in 2023 for 340B hospitals to provide reports on how 340B Program savings are used to benefit the community.[81] Minnesota passed a broader reporting law with eight new annual reporting requirements, such as total acquisition and payment costs for 340B drugs, which are applicable to all covered entities.[82] As legislative sessions begin in 2024, additional developments may occur at the state level that may impact the activities of 340B Program stakeholders.

2024 Outlook

340B Program sales have continued to rise, despite manufacturer restrictions on contract pharmacies. Looking into 2024, the tug-of-war between manufacturers and covered entities is likely to continue, with each group seeking mechanisms to, respectively, retract or expand 340 pricing access within HRSA's rule-making vacuum. These mechanisms are likely to trigger additional agency actions and legal challenges, adding to an evolving body of law regulating manufacturer arrangements with covered entities. With Congress mired in other disputes, the scope of the 340B Program and access to its pricing is likely to continue to be a moving target.

Copay Accumulators In Limbo: HHS Appeals D.C. District Court Vacatur of 2021 Copay Accumulator Rule

By: Scott Liebman and Cortney Inman

On September 29, 2023, the United States District Court for the District of Columbia ruled in favor of plaintiff patients and patient advocacy groups, vacating a Trump-era U.S. Department of Health and Human Services ("HHS") and Centers for Medicare and Medicaid Services ("CMS") regulation concerning the permissibility of so-called "copay accumulators."[83] Under the regulation—the 2021 HHS Notice of Benefit and Payment Parameters ("NBPP")—insurance companies were given free rein to decide whether to exclude manufacturer assistance when calculating whether a patient has met their annual cost-sharing obligation.[84] The court held that this rule was arbitrary and capricious because it authorized conduct "based on contradictory interpretations of the same statutory and regulatory provisions" and essentially delegated interpretation of the statute and regulation to the regulated entity itself.[85]

Background

Under the Patient Protection and Affordable Care Act ("ACA"), insurance companies are solely responsible for the insured individual's remaining medical expenses for that year once the insured individual meets their annual "cost-sharing" obligation.[86] The ACA defines "cost-sharing"

to include "(i) deductibles, coinsurance, copayments, or similar charges; and (ii) any other expenditure required of an insured individual which is a qualified medical expense . . . with respect to essential health benefits covered under the plan."[87] Similarly, the agencies adopted a regulatory definition of "cost sharing" to mean "any expenditure required by or on behalf of an enrollee with respect to essential health benefits; . . . includ[ing] deductibles, coinsurance, copayments, or similar charges."[88]

To help defray the costs of expensive specialty medications, some drug manufacturers offer financial assistance, such as coupons, to eligible patients.[89] When a patient presents these coupons at the pharmacy, both the pharmacy and insurance company receive the same payment they would otherwise receive; the only change is that the drug company "subsidize[s] the patient's purchase of the drug."[90] In response to these programs, insurance companies began instituting "copay accumulators," which exclude manufacturer assistance from the patient's cost-sharing obligation.[91]

HHS NBPP Regulations

HHS first opined on such accumulator programs in 2019, issuing the "2020 NBPP," which permitted insurance companies to exclude manufacturer assistance from cost-sharing only for "prescription brand drugs that have an available and medically appropriate generic equivalent."[92] In so doing, HHS reasoned that manufacturer assistance has the potential to result in market distortion by shielding patients from the true cost of expensive name brand drugs when a less expensive generic treatment is available.[93]

However, less than a year later, HHS loosened the regulation in favor of insurance companies. Under the 2021 NBPP, manufacturer assistance "may be, but [is] not required to be, counted toward the annual limitation on cost sharing," removing any reference to the availability of a generic equivalent.[94] Furthermore, in the preamble to the rule, HHS provided two conflicting interpretations of "cost sharing," essentially saying that if the insurer decides to exclude manufacturer assistance when calculating the patient's cost-sharing obligation, then such assistance is not included within the definition of "cost-sharing" and vice versa.[95] In justifying this change, HHS cited confusion regarding a potential conflict with a 2004 IRS guidance and "the desire to provide insurers with 'flexibility.'"[96] Additionally, HHS dismissed concerns that expanding authorization for accumulators would raise patient drug costs, noting that it was unlikely that insurance companies would change existing practices following adoption of the rule.[97]

Case Aftermath and Looking Forward

As aforementioned, the D.C. District Court vacated the 2021 NBPP as arbitrary and capricious given that the contradictory basis of the rule rendered it unable to be rehabilitated on remand.[98] Despite plaintiffs' insistence, the court declined to interpret whether the statutory or regulatory definition of the term "cost-sharing" includes manufacturer assistance.[99] Nonetheless, the judge did seem sympathetic to the plaintiffs' position, noting that the court "would conclude that the regulatory definition unambiguously requires manufacturer assistance to be counted as 'cost sharing.'"[100]

This decision has been viewed as a clear win for patients, patient advocacy groups, and drug manufacturers. In particular, industry stakeholders have unanimously interpreted the opinion as reinstating the 2020 NBPP, which limited the use of copay accumulators to circumstances where a generic equivalent is available, thereby permitting patients to utilize manufacturer assistance without the added difficulty of reaching potentially high deductibles after such assistance runs out. However, recent HHS activity has rendered the path forward uncertain.

On November 27, 2023, HHS has filed a Notice of Appeal to the D.C. Circuit as well as a Motion to Clarify the September Memorandum Opinion. In the Motion to Clarify, the agency indicated that it plans to address issues related to the NBPP in future rulemaking, including whether manufacturer assistances qualifies as cost-sharing under the ACA. More interestingly, however, the agency also instructed that it will not enforce the 2020 NBPP against insurers for the time being, essentially undermining the court's instructions.

With the current status of copay accumulators in flux, this is certainly a case to watch going forward. In particular, industry should keep an eye on: (1) future HHS rulemaking; (2) what response, if any, the court will have to HHS's proposed enforcement policy; and (3) whether the district court's decision is upheld on appeal.

KEEP YOUR EYE ON

Office of Inspector General Compliance Program Guidance

By: Eve Costopoulos

In April, the Office of Inspector General, Department of Health and Human Services (OIG) announced that it would make changes to its existing body of healthcare compliance program guidance (CPGs) as part of its current Modernization Initiative.[101] These CPGs were directed at various segments of the health care industry and provided specific guidance on risks posed by healthcare industry practices. To kick off the initiative, in November OIG issued a new general compliance program guidance (GCPG) applicable to individuals and entities in all segments of the health care industry. It provides information about relevant federal laws, compliance program infrastructure, OIG resources and other general information useful to the health care compliance community. The GCPG is presented in a new format that is easy to read and includes links to OIG documents, reference citations and other helpful resources. OIG plans to update existing industry-specific compliance program guidance (ICPG) that will be tailored to address fraud and abuse risk areas specific to a particular industry and describing the compliance measures that industry could take to reduce these risks.[102] OIG anticipates publishing the first ICPGs to address Medicare Advantage and nursing facilities in 2024.

The GCPG is a valuable resource for compliance professionals working both within and in support of health care organizations. It includes past OIG guidance regarding basic compliance practices across a wide spectrum of industries and new guidance based upon experience from negotiating and monitoring corporate integrity agreements and from enforcement actions and investigations. Of particular note is guidance pertaining to the role of a Compliance Officer, where OIG confirms that the Compliance Officer should i) report to the chief executive officer (CEO) of the organization with direct access to the board or report directly to the board, ii) have equal stature to other senior leaders, and iii) be an advisor to the CEO, the board and senior leaders on compliance risks facing the company. The CPGC specifically states that the Compliance Officer should not "lead or report to the entity's legal or financial functions and should not provide the entity with legal or financial advice or supervise anyone who does."[103] The question of "to whom should a compliance officer report?" has been discussed for years among life sciences companies and with this GCPG, the question appears to be answered.[104]

The GCPG includes tips, best practices and links to a variety of resources, including advisory opinions, special fraud alerts, bulletins and reports, compliance toolkits and corporate integrity agreements. Bottom line—the GCPG should be required reading for legal and compliance professionals working within and alongside industries impacted by the GCPG.

From Good Reprint Practices To SIUU Communications: What Firms Need To Know

By: Dominick DiSabatino and Justine Lei

2023 was a busy year for the Food and Drug Administration ("FDA"). The agency published dozens of draft and final guidances with the promise of more in the new year. One of these is the Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products, Questions and Answers (the "SIUU Draft Guidance"). The SIUU Draft Guidance builds upon FDA's 2014 draft guidance on the same subject, Distributing Scientific and Medical Publications on Unapproved New Uses — Recommended Practices, which itself was a revision to FDA's 2009 guidance Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices. As with other guidances, FDA remains thoughtful and intentional with its regulation manufacturing firms and shows that the agency seeks to evolve its thinking alongside the rapid use and incorporation of new technologies and relatedly, the ever-changing modes and methods of communication.

2023 SIUU Draft Guidance

The SIUU Draft Guidance includes several changes to the scope and applicability of this guidance on communications between manufacturing firms and healthcare providers, but explicitly does not address communications where a firm is responding to unsolicited requests, which is addressed in FDA's guidance document on Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices (December 2011). In the SIUU Draft Guidance, FDA focuses on communications for scientific information on unapproved uses, or "SIUU", of an approved or cleared medical product, referring to these communications as "SIUU Communications", and emphasizing that SIUU Communications should be (1) "truthful, non-misleading, factual, and unbiased" so that (2) a healthcare provider has all the information necessary to "interpret the strengths and weaknesses and validity and utility of the information" provided in a SIUU Communication.

FDA also tasks manufacturing firms with satisfying two requirements required for compliant SIUU Communications: (1) to ensure that any study or analysis discussed in a source publication that serves as a foundation for a SIUU Communication should be "scientifically sound" and (2) to provide information that is pertinent to healthcare provider making clinical practice decisions for the care of an individual patient or "clinically relevant". FDA provides guidance on what constitutes "scientifically sound" source publications that can provide "clinically relevant information," stating that randomized, double-blind, controlled trials are most likely to provide information that is both scientifically sound and clinically relevant. FDA also notes that other well-designed and well-conducted trials are also generally able to provide scientifically sound and clinically relevant information. Given FDA's updated guidance on this issue, manufacturing firms may want to evaluate their SIUU Communications and ensure that source publications relied upon in SIUU Communications satisfy the FDA's requirements in the SIUU Draft Guidance.

In addition to providing scientifically sound information that is clinically relevant, SIUU Communications must also be truthful, non-misleading, factual, and unbiased and such communications should include certain statements,

disclosures, and information including but not limited to:

- A statement that the unapproved use(s) of the medical product has not been approved by FDA and that the safety and effectiveness of the medical product for the unapproved use(s) has not been established.
- A statement disclosing (i) FDA-approved use(s) of the medical product, including any limitations of use specified in the FDA-required labeling, and (ii) any limitations, restrictions, cautions, or warnings described in the FDA-required labeling about the unapproved use(s).
- Information on source publications relied upon in the SIUU Communication.

In addition, there are certain techniques and statements that should be included in or excluded from SIUU Communications to ensure such communications are not misleading, including but not limited to:

- Disclosures should be clearly and prominently presented.
- Persuasive marketing techniques should be excluded so as to avoid the possibility that FDA will consider such persuasive techniques as evidence of promoting an intended use of the product.
- SIUU Communications should be provided to healthcare providers in a manner that is separate and distinct from any promotional communications about the approved uses of medical products.
- SIUU Communications should use plain language to minimize misunderstanding of, and aid in the accurate comprehension and consideration of, scientific information shared in such communications.

For other considerations of note regarding SIUU Communications, please see our Blog Post on SIUU Communications: What Firms Need to Know | FDA Law Update (fdalawblog.com)

2024 Outlook

The SIUU Revised Guidance is in line with many of the other guidance released by the agency this year, which memorialized FDA's intent to encourage research and development of new drugs and medical products and utilization of novel techniques in doing so. This is reflected in many of the draft and final guidance related to clinical trials and development of medical products, including but not limited to draft guidances related to increasing inclusion of different populations, expanding areas of focus in the orphan drug and rare disease space, initiating studies in areas such as psychedelics, and embracing efforts to use artificial intelligence, machine learning, and software.

With all of these efforts to embrace novel approaches to the existing clinical trial and development processes, it is no surprise that FDA wants to ensure that manufacturing firms are communicating accurate information to healthcare providers who in turn advise patients' healthcare decisions. It is especially important that manufacturing firms seeking to embrace further exploration of novel uses of their existing FDA approved medical products, are communicating any newly discovered unapproved uses in a manner that reflects the most updated clinical research and results and provides healthcare providers with all information necessary to advise patients of the benefits and risks of using an approved medical product for unapproved uses.

As we continue into 2024, manufacturing firms should continue to ensure that all communications are in line with FDA and other federal agency requirements, and that such firms have compliance programs and policies in place that govern employees actions and are in line with regulatory requirements and recommendations, such as those set forth in the Office of Inspector General's General Compliance Program Guidance. Though many guidances released by federal agencies this year, including by FDA, are recommendations and not requirements, there are plenty of opportunities for manufacturing firms to fall into regulatory hot water. To minimize the possibility of and exposure to enforcement actions, manufacturing firms should take stock of the SIUU Draft Guidance and other guidances released in 2023 and ensure strategy and approach for 2024 and beyond reflect the FDA and other agencies most recent recommendations and requirements.

KEEP YOUR EYE ON

Abiomed Warning Letter and Digital Health Software/Labeling

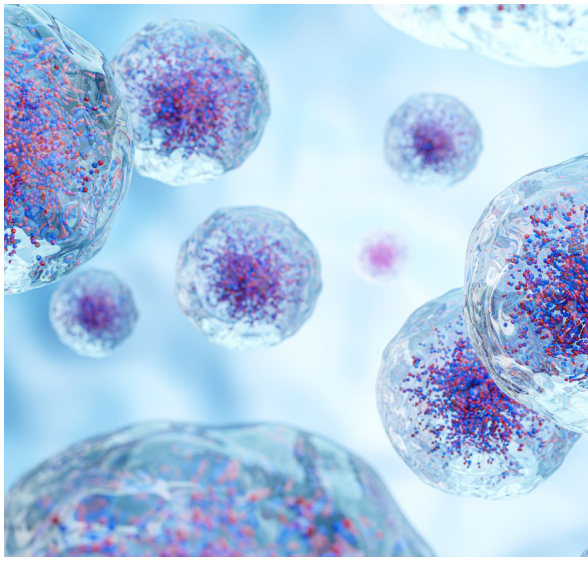
By: Dominick DiSabatino and Arushi Pandya

As seen in FDA's exercise of enforcement discretion in its Warning Letter to Abiomed Inc. (Abiomed), device-enabling software, including Clinical Decision Support (CDS) Software received notable attention from FDA in 2023, and is expected to remain a priority in the upcoming year. FDA issued a Warning Letter to Abiomed for promotion of a CDS Software that incorporated remote monitoring functions, including device performance notifications and alarms, without pre-market approval.[105]

What constitutes CDS Software is context-specific, but CDS Software generally provides health care providers and patients with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care.[106] FDA has established classification criteria for CDS Software which is not a medical device, all of which must be met to be classified as Non-Device CDS Software and exempt from FDA regulation.[107] While Abiomed argued the CDS Software was not a medical device because the CDS Software provided decision support to health care providers, FDA disagreed and found the CDS Software provided "patient-specific medical information to detect a life-threatening condition and display time-critical alarms intended to notify a health-care provider" which constituted device functions.[108] The Warning Letter indicates FDA's narrow construction of Non-Device CDS Software, as well as its focus on promotional product claims in the software space. Device-enabling software is likely to remain a key area of FDA scrutiny in 2024, potentially resulting in additional enforcement actions.

Non-Competition Provisions in M&A Transactions

By: Jeff Fessler and Keren Baruch

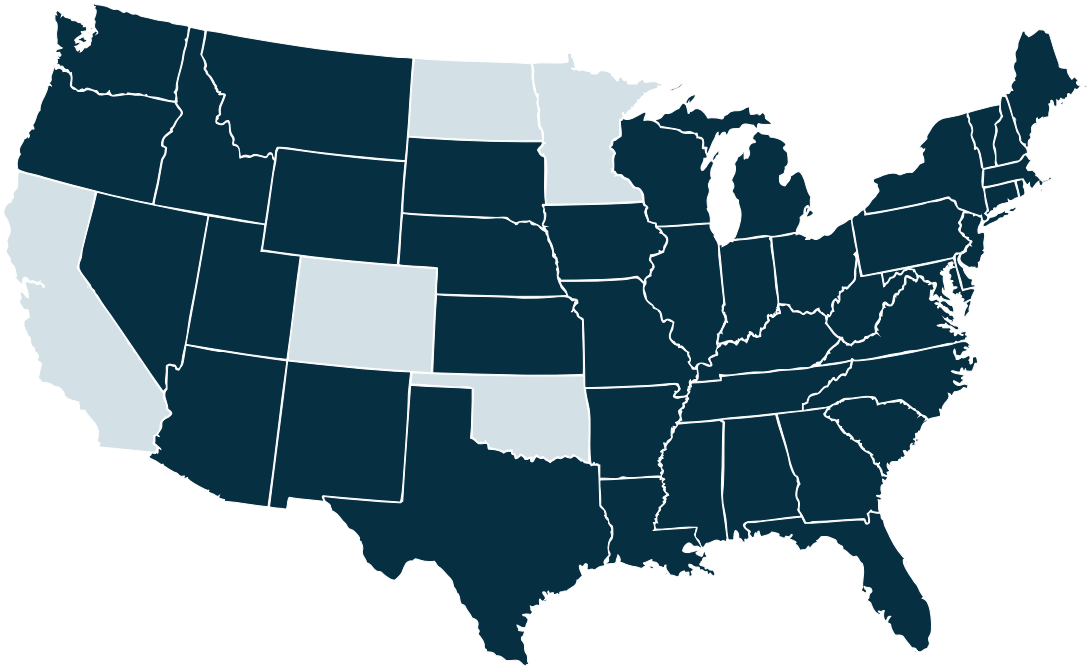


In 2024, the expectation is that M&A activity among life sciences companies will increase. Non-compete agreements, which are typical in life sciences M&A transactions, have recently come under attack at the federal and state level.

Non-competition provisions are commonly used in two contexts in an M&A transaction: (1) employment-related non-competition provisions and (2) sale of business non-competition provisions. In the first context, employment agreements may be transferred from one entity to another, or employees may enter into new employment agreements with acquirors, and such agreements may include non-competition provisions prohibiting the employees from competing with their respective employers within a

certain industry, geography and/or for a certain period of time after their employment terminates. In the second context, an individual or entity seller in an M&A transaction may enter into an agreement with the acquiror prohibiting such seller's ability to compete with an acquiror for a specific period of time following the closing of the transaction.

Five states have banned employment-related non-competition clauses: (1) California, (2) Colorado, (3) Oklahoma, (4) North Dakota and (5) Minnesota.



California

California was the first state to implement a broad non-compete ban. On September 1, 2023, Sente Bill No. 699 was passed to expand the ban. Effective January 1, 2024, civil liabilities can be imposed on employers who either enter into, or attempt to enforce, a non-competition agreement, regardless of where or when such agreement was entered into. Employees will have a right to bring a private action against employers that violate the rule. California's ban extends to include customer and client non-solicitations. California employers who previously included post-employment restrictions in their agreements knowing that they may not be enforceable will no longer be able to do so without facing a risk of liability under this law. California continues to allow non-compete agreements in three limited circumstances: (1) upon the sale of goodwill or a business, (2) dissolution of a partnership or (3) dissolution or sale of a limited liability company.

Colorado

On June 8, 2022, Colorado Governor Jared Polis signed HB 22-1317 into law, which prohibits the enforceability of non-competition agreements executed after August 1, 2022. The ban contains an exception for workers making more than $112,5000 in 2023. Colorado's ban contains four exceptions: (1) a contract for the purchase and sale of a business or the assets of a business, (2) a contract for the protection of trade secrets, (3) a contract authorizing recovery for education and training expenses of an employee who has served the employer for less than two years and (3) a contract with an executive or manager, or professional staff to executives or managers. If a non-compete falls within one of these four carve-outs, it must be limited both in jurisdiction and time. C.R.S. Section 8-2-113(3) indicates that non-competes restricting a physician's ability to practice medicine are void, which is broad enough to apply in the context of a business sale.

Oklahoma

According to Oklahoma Statute Section 15-219A, non-competition provisions in employment agreements are void. Oklahoma's non-compete ban contains statutory exceptions for: (1) a sale of goodwill, after which the seller may agree to refrain from carrying on a similar business within a specified geographic area so long as the person deriving title to the goodwill carries on the business, (2) a dissolution of a partnership, after which partners may agree that none of them will carry on a similar business within a specified geographic area, and (3) employee and customer non-solicitation restrictions.

North Dakota

According to Chapter 9-08 of the North Dakota Century Code, non-competition provisions are void and unenforceable in North Dakota. North Dakota's non-compete ban contains an exception in the context of (1) the sale of the good will of a business and (2) the dissolution of a partnership, limited liability company or corporation.

Minnesota

On May 24, 2023, Minnesota Governor Tim Walz signed into law a bill prohibiting employment-related non-competition agreements entered into on or after July 1, 2023. The ban applies to all employees, regardless of title, and independent contractors. The ban does not apply retroactively, so agreements entered into prior to July 1, 2023 remain enforceable. Minnesota's non-compete ban contains an exception for non-compete agreements entered into in connection with (1) a sale of business and (2) the dissolution of a business. The non-compete must be reasonable with respect to time, jurisdiction, and type of prohibited business.

New York

On June 20, 2023, the New York Legislature passed Bill S3100A/A1278B prohibiting non-compete agreements between an employer and employee. Employees may be entitled to liquidated damages of up to $10,000 under this proposed legislation. The bill does not include a carve-out for a non-competition agreement entered into in connection with an M&A transaction analogous to the exceptions included in the California, Colorado, North Dakota, Minnesota and Oklahoma laws. If the bill is passed into law, non-competition provisions entered into between buyers and sellers in the context of an M&A transaction in New York may be unenforceable, and sellers may be able to sell a company, and immediately form a new company with a business competitive to the business it just sold.

There is no current federal ban on non-compete agreements. However, the Federal Trade Commission (FTC) released a proposal on January 5, 2023, pursuant to Sections 5 and 6(g) of the FTCA Act, to prohibit non-competes. The proposed rule would define the term "non-compete clause" as "a contractual term between an employer and a worker that prevents the worker from seeking or accepting employment with a person, or operating a business, after the conclusion of the worker's employment with the employer." The ban would be effective on a retroactive basis. The definition would exclude other types of restrictive covenants, such as non-disclosure agreements and client or customer non-solicitation provisions. The FTC's proposed rule specifically excludes non-compete agreements that are entered into in connection with the sale of all or substantially all of a business entity's assets or the sale or other disposal of all of a person's ownership interest in a business entity.

A federal ban on non-competition provisions will change the employer/employee landscape across the United States, and a broad non-compete ban in New York without carveouts for non-competition provisions in the context of an M&A transaction may deter companies from incorporating entities in New York, conducting business in New York and/or hiring employees in New York.

The new laws and regulations described above make it more challenging to protect companies confidential and trade secret information in M&A transactions. Given the clear trend it is imperative that parties to an M&A transaction consider alternatives such as nondisclosure agreement or non-solicitation agreements that may be considered to be less burdensome with respect to restrictions.

KEEP YOUR EYE ON

Modernization of Clinical Trial Process

By: Eve Costopoulos and Justine Lei

This year FDA continued to advance its ongoing efforts to modernize and enhance the agency's overall approach to the drug development and drug regulation processes. Learning from the COVID-19 public health emergency, FDA is seeking to implement novel digital health technologies that can help support patient recruitment and data collection from historically underrepresented populations and develop adaptive clinical trial designs that can address diseases and conditions impacting everyone from the general population to the rare disease population and better predict how medical products developed from these clinical trials will impact the general population.. Of course, these new initiatives are combined with FDA's continued oversight of clinical trial activities.

For instance, in furtherance of the additional powers granted to it pursuant to the Food and Drug Omnibus Reform Act of 2022 (FDORA) to regulate clinical trials and research related activities, FDA issued guidance confirming new requirements for the accelerated approval process, including that i) studies be underway prior to the granting of accelerated approval, ii) post-approval studies begin within a specified time frame from approval, iii) progress reports are submitted regarding progress of post-approval studies, and iv) products approved under the accelerated approval process be withdrawn expeditiously under certain circumstances.

Other features of FDORA include expanded powers for FDA to i) inspect bioresearch monitoring facilities, ii) request records and other information related to inspections of medical device manufacturing facilities, iii) conduct remote inspections of such facilities, iv) regulate medical device compliance with cybersecurity requirements and v) to require clinical trial sponsors to submit diversity action plans for certain late-stage drug trials, including all phase 3 trials, as well as most medical device studies. Pursuant to the powers granted under FDORA, FDA has been convening public workshops with appropriate stakeholders to solicit input regarding enhancing enrollment in clinical studies of historically underrepresented populations.[109]

FDA also issued additional clinical-trial related guidance i) for the use of externally controlled clinical trials (trials that would compare patients receiving an investigational treatment within the trial to patients outside of the trial not receiving the same treatment) to provide evidence of the safety and efficacy of a drug[110], ii) for decentralized clinical trials that occur at locations other than traditional clinical trial sites (advocating that trial-related activities in patients' homes may improve clinical trial diversity, engagement, and retention of patients that may have challenges accessing traditional clinical sites[111], iii) relating to recommendations for good clinical practices intended to modernize the design and conduct of clinical trials to make them more agile without compromising data integrity or participant protections[112]. Further, FDA has announced a multifaceted approach to the use of digital health technologies in drug development, that includes workshops, engagement with shareholders, shared learning, development of policy and analytic tool development and publication of guidance documents[113].

For manufacturing companies, clinical trial sponsors and investigators, and those subject to FDA drug regulations, the clinical trial guidances issued by FDA in 2023 evidence the FDA's shift from traditional clinical trial approaches and reflect its current thinking and future-looking expectations for clinical trials. Companies and persons engaged in clinical trials should consider evaluating their compliance programs to ensure that applicable clinical study policies and procedures are updated and reflect the FDA's recently released and existing clinical trial guidances. Further, it will be important to keep an eye on FDA's enforcement of these new requirements to avoid incurring FDA enforcement actions and facing possible delays in the FDA's approval or clearance of a medical product.

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[18] https://www.justice.gov/usao-edtx/pr/california-man-convicted-health-care-kickback-conspiracy.

[19] https://www.justice.gov/opa/pr/texas-laboratory-agrees-pay-59-million-settle-allegations-kickbacks-third-party-marketers-and.

OPDP Year in Review Endnotes

[20] See https://www.fda.gov/media/169419/download; https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/astrazeneca-pharmaceuticals-lp-664789-08042023; https://www.fda.gov/media/171460/download?attachment; https://www.fda.gov/media/173730/download?attachment; https://www.fda.gov/media/173696/download?attachment.

[21] U.S. Food and Drug Administration et al. (2018) Medical Product Communications That Are Consistent With the FDA-Required Labeling Questions and Answers, Guidance for Industry. Available at: https://www.fda.gov/media/133619/download (the "CFL Guidance").

[22] https://www.fda.gov/media/172712/download?attachment; See also U.S. Food and Drug Administration et al. (2023) Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer (DTC) Promotional labeling and Advertisements, Guidance for Industry. Available at:https://www.fda.gov/regulatory-information/search-fda-guidance-documents/presenting-quantitative-efficacy-and-risk-information-direct-consumer-dtc-promotional-labeling-and.

[23] https://www.fda.gov/media/169803/download.

KEEP YOUR EYE ON: Challenges to *Chevron* Endnotes

[24] Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., et. al., 467 U.S. 837 (1984).
[25] West Virginia v. Environmental Protection Agency, et. al., 597 U.S. ___ (2022).

[26] Docket No. 22-451.

[27] Docket No. 22-1219.

Federal Antitrust Enforcement Activity Promoting Generic and Biosimilar Competition Endnotes

[28] In December, the agencies emphasized their commitment to enforcement in these industries with a statement by the FTC, DOJ and the U.S. Department of Health and Human Services (HHS) highlighting their activities and achievements in the life sciences and healthcare arenas and reiterating their commitment to data sharing for the purpose of identifying transactions and other conduct that might otherwise evade detection by the federal antitrust enforcers. The agencies endorsed a "whole government" approach to protecting competition in these industries and FTC, DOJ and HHS each will be naming dedicated competition officers in 2024 to help lead these efforts. Fed. Trade Comm'n, Press Release, "FTC, DOJ and HHS Work to Lower Health Care and Drug Costs, Promote Competition to Benefit Patients, Health Care Workers" (Dec. 7, 2023), available at, https://www.ftc.gov/news-events/news/press-releases/2023/12/ftc-doj-hhs-work-lower-health-care-drug-costs-promote-competition-benefit-patients-health-care.

[29] Fed. Trade Comm'n, Policy Statement, "Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book" (Sept. 14, 2023), available at, https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf.

[30] See Fed. Trade Comm'n, Press Release, "FTC Challenges More Than 100 Patents as Improperly Listed in the FDA's Orange Book" (Nov. 7, 2023), available at, https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book.

31 Case No. 2:23-cv-00836 (W.D. Pa) (Fed. Trade Comm'n Br. As Amicus Curiae filed Nov. 20, 2023), available at, https://www.ftc.gov/system/files/ftc_gov/pdf/p082105sanofiamicusbrief.pdf. See also, *Sage Chemical, Inc. v. Supernus Pharmaceuticals, Inc.*, case no. 1:22-cv-01302 (D. Del) (Fed. Trade Comm'n Br. As Amicus Curiae filed Mar. 22, 2023)(noting several antitrust issues raised by defendants' motion to dismiss relating to brand drug manufacturers' exclusionary conduct to impede generic competition and specifying that narrow or single-brand or single-manufacturer markets are appropriate when there are no adequate substitutes).

Amgen Inc. v. Sanofi: How the Supreme Court's Recent Decision Impacts Patents in Life Sciences Endnotes

[32] Section 112(a) of the Patent Act requires that a patent specification includes "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art…to make and use the same." This enablement requirement is to ensure that an invention is communicated to the interested public in a meaningful way. Patent claims that are not supported by an enabling disclosure may be deemed invalid.

[33] See Amgen Inc. v. Sanofi, 872 F. 3d 1367, 1371 (CA Fed. 2017)

[34] Id.

[35] Amgen Inc. v. Sanofi

[36] Holland Furniture Co. v. Perkins Glue Co., 277 U. S. 245

[37] Baxalta Inc. v. Genentech, Inc., 81 F.4th 1362 (Fed. Cir. 2023)

[38] Id. at 1366

[39] Id.

[40] Ex parte KARL-JOSEF KALLEN, THOMAS KRAMPS, MARGIT SCHNEE, BENJAMIN PETSCH, and LOTHAR STITZ, Appeal 2022-004839 (PTAB, 2023)

[41] Ex parte THE PEN, Appeal 2022-001764 (PTAB, 2023)

[42] Amgen Inc. v. Sanofi

[43] Although the FDCA does not define the term, FDA defined LDT in the proposed rule as "an IVD that is intended for clinical use and that is designed, manufactured, and used within a single laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform high-complexity testing (i.e., is a CLIA-certified high complexity lab)." 88 Fed. Reg. 68009.

[44] See LDT Proposed Rule, Docket No. 2023-141, CDRH (last visited Jan 1, 2024).

[45] See, e.g., FDA Proposed Rule To Regulate LDTs As Medical Devices Would Slow Development Of Critical Lab Tests And Should Be Withdrawn, ACLA Urges, ACLA (Dec. 4, 2023) ("ACLA steadfastly maintains that legislation is the right – and only – approach for further oversight of LDTs. ACLA believes the proposed rule represents regulatory overreach and should be withdrawn").

[46] See Press Release, FDA Proposes Rule Aimed at Helping to Ensure Safety and Effectiveness of Laboratory Developed Tests, U.S. Food & Drug. Admin. (Sept. 29, 2023).

[47] IVD is defined as "reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequalae, and intended for use in the collection, preparation, and examination of specimens taken from the human body. These products are devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the act), and may also be biological products subject to section 351 of the Public Health Service Act." 21 C.F.R. § 809.3(a).

[48] Device is defined as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory which is … intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease." 21 U.S.C.A. § 321(h)(1).

[49] See Draft Guidance, Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs), U.S. Food & Drug Administration (Oct. 3, 2014).

[50] See Discussion Paper on Laboratory Developed Tests (LDTs), U.S. Food & Drug Administration (Jan. 13, 2017).

[51] See Press Release, Dr. Bucshon, DeGette Release Draft of the Diagnostic Accuracy and Innovation Act (DAIA) (Mar. 21, 2017).

[52] See U.S. Congress, House, Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2021, HR 4128, 117th Cong., 1st sess., introduced in House June 24, 2021.

[53] See Press Release supra FN 4.

[54] See 21 CFR Part 803.

[55] See 21 CFR Part 806.

[56] See 21 CFR Part 807.

[57] See 21 CFR Parts 801 and 809, Subpart B.

[58] See 21 CFR Part 812.

[59] See Current Good Manufacturing Practices ("CGMP") rules at 21 CFR Part 820.

[60] See the Pre-Market Application ("PMA") process at 21 CFR Part 814.

[61] See the 510(k) process at 21 CFR Part 807, Subpart E, and/or the de novo request process at 21 CFR Part 860, Subpart D.

[62] See In Comments to FDA, AdvaMed Maintains Support of Agency's Authority to Regulate LDTs, AdvaMed (Dec. 12, 2023).

[63] See ACLA Opposes Unilateral FDA Action to Regulate Laboratory Developed Tests under Medical Device Authority, ACLA (Sept. 29, 2023).

[64] See Laboratory Developed Tests, FDA (Oct. 30, 2023).

[65] CDRH Proposed Guidances for FY2024, FDA (Oct. 10, 2023).

KEEP YOUR EYE ON: Efforts to Control Drug Prices

[66] See FACT SHEET: Biden-Harris Administration Announces First Ten Drugs Selected for Medicare Price Negotiation, U.S. White House (Aug. 29, 2023).

[67] https://fortune.com/well/2023/10/25/medicare-drug-price-negotiation-affect-prescription-costs/.

[68] See, e.g., *National Infusion Center Association v. Becerra*, 1:2023cv00707, (W.D. Tex – June 21, 2023); Drugmakers, Trade Groups Push Back Against Medicare Drug Price Negotiations, Politico (Aug. 29, 2023).

[69] Fed. Trade Comm'n, "Report on Rebate Walls," (May 28, 2021).

[70] Fed. Trade Comm'n, Press Release, "FTC Launches Inquiry Into Prescription Drug Middlemen Industry" (June 7, 2022), available at, https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry.

[71] Fed. Trade Comm'n, Press Release, "FTC Deepens Inquiry into Prescription Drug Middlemen" (May 17, 2023), available at, https://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-deepens-inquiry-prescription-drug-middlemen.

[72] Fed. Trad Comm'n, Statement, "Federal Trade Commission Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports That No Longer Reflect Current Market Realities (july 20, 2023), available at, https://www.ftc.gov/system/files/ftc_gov/pdf/CLEANPBMStatement7182023%28OPPFinalRevisionsnoon%29.pdf.

340B: A Shifting Landscape Endnotes

[73] 42 U.S.C. § 256b ("340B Statute").

[74] See Pharmaceutical Research and Manufacturers of America v. U.S. Department of Health and Human Services, 43 F. Supp. 3d 28 (D.C. Cir. 2014).

[75] 61 Fed. Reg. 43, 549 (Aug. 23, 1996).

[76] 75 Fed. Reg. 10, 272 (Mar. 5, 2010).

[77] See Sanofi Aventis U.S. LLC v. U.S. Department of Health & Human Services, 48 F.4th 696 (3rd Cir. 2023).

[78] See Genesis Health Care, Inc. v. Becerra, et. al., No. 4:19-cv-01531-RBH (S. Car. 2023).

[79] 61 Fed. Reg. 55156, 55157 (Oct. 24, 1996).

[80] H.B. 548, 2023 Leg. (La. 2023).

[81] 22 Maine Rev. Stat. § 1728(2).

[82] SF 2995, 93rd Leg. (Minn. 2023).

Copay Accumulators In Limbo: HHS Appeals D.C. District Court Vacatur of 2021 Copay Accumulator Rule Endnotes

[83] HIV & Hepatitis Pol'y Inst. v. U.S. Dept. of Health & Human Servs., No. 22-2604 (D.D.C. 2023).

[84] See id. at 7-8 (citing 85 Fed. Reg. 29164, 29230-35, 29261 (May 14, 2020) (codified at 45 C.F.r. § 156.130(h)).

[85] See id. at 15-17.

[86] Id. at 2.

[87] 42 U.S.C. § 18022(c)(3)(A).

[88] 45 C.F.R. § 155.20.

[89] HIV & Hepatitis Pol'y Inst., No. 22-2604 at 3.

[90] See id.

[91] Id. at 4.

[92] Id. at 5; 84 Fed. Reg. 17454, 17568 (Apr. 25, 2019) (codified at 45 C.F.R. § 156.130(h); version effective from June 24, 2019 to July 12, 2020).

[93] 84 Fed. Reg. at 17544.

[94] 85 Fed. Reg. at 29261.

[95] See id. at 29234 ("For [health insurance] issuers who elect to include these amounts towards a consumer's annual limitation on cost sharing, the value of direct drug manufacturer support would be considered part of the overall charges incurred by the enrollee. For [health insurance] issuers who elect not to count these amounts towards the consumer's annual limitation on cost sharing, the value of the direct drug manufacturer support would be considered a reduction in the amount that the enrollee incurs or is required to pay.").

[96] HIV & Hepatitis Pol'y Inst., No. 22-2604 at 7.

[97] Id. at 8.

[98] Id. at 20.

[99] See id. at 17, 20, 23-24.

[100] Id. at 23.

KEEP YOUR EYE ON: Office of Inspector General Compliance Program Guidance Endnotes

[101] 88 Fed. Reg. 25000 (April 25, 2023).

[102] Id. Individual GCPs were developed for i) hospitals, ii) home health agencies, iii) clinical laboratories; iv) third-party medical billing companies; v) the durable medical equipment, prosthetics, orthotics, and supply industry; vi) hospices; vii) Medicare Advantage (formerly known as Medicare+Choice) organizations; viii) nursing facilities; ix) physicians; x) ambulance suppliers; and xi) pharmaceutical manufacturers. OIG anticipates publishing the first ICPGs to address Medicare Advantage and nursing facilities in 2024.

[103] Id. at 39.

[104] OIG General Compliance Program Guidance November 2023 | FDA Law Update (fdalawblog.com)

KEEP YOUR EYE ON: Abiomed Warning Letter and Digital Health Software/Labeling Endnotes

[105] See FDA Warning Letter, Abiomed Inc. (Sept. 19, 2023), available at: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/abiomed-inc-663150-09192023.

[106] Office of the National Coordinator for Health Information Technology, "What is Clinical Decision Support (CDS)?" available at: https://www.healthit.gov/topic/safety/clinical-decision-support.

[107] See FDA Guidance, Clinical Decision Support Software, U.S. Food & Drug Admin. (Sept. 28, 2022), available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software.

[108] Id.

KEEP YOUR EYE ON: Modernization of Clinical Trial Process Endnotes

[109] Discussing Approaches to Enhance Clinical Study Diversity Public Workshop, November 29-30, 2023, https://www.fda.gov/drugs/news-events-human-drugs/discussing-approaches-enhance-clinical-study-diversity-public-workshop-11292023.

[110] Considerations for the Design and Conduct of Externally Controlled Trials for Drug and Biological Products, Draft Guidance, February 2023, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-design-and-conduct-externally-controlled-trials-drug-and-biological-products.

[111] Decentralized Clinical Trials for Drugs, Biological Products, and Devices Guidance for Industry, Investigators, and Other Stakeholders, Draft Guidance, May 2023, https://www.fda.gov/media/167696/download.

[112] E6(R3) Good Clinical Practice (GCP), May 19, 2023, https://www.fda.gov/media/169090/download.

[113] Framework for the Use of Digital Health Technologies in Drug and Biological Product Development, March 2023, https://www.fda.gov/media/166396/download.

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